CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA01.00**
TITLE: Personnel	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for hiring and training personnel for employment in wholesale drug distribution.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Personnel employed at the distribution center shall have appropriate education and/or experience and an acceptable level of proficiency to perform their job. This shall be accomplished through a pre-employment screening process which includes:

   a.) A detailed review of the employment application.

   b.) A thorough interview process.

   c.) A written consent by prospective employees to each of the following:

      i.) Physical examination

      ii.) Drug test

      iii.) Investigation of their background and fitness for the position for which they are applying

      iv.) DEA file check

      v.) Criminal record check

2.) Reference checks and verification of employment application information shall be included when the results of the pre-employment screening process warrant further review and evaluation of the applicant.

3.) The facility shall not allow a prospective employee to commence working in the facility until results are received from the pre-employment screening process.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA01.00**
TITLE: Personnel	**ISSUE DATE:**
	PAGE: 3 of 3

4.) The facility shall provide a copy of the PDMA Employee Guide **(Exhibit EA01.00)** to all employees who handle prescription products and receipt of the guide shall be documented.

5.) The facility shall provide training to each employee in the following areas as they relate to prescription drugs and the employee's specific job function:

a.) Storage

b.) Examination of materials during receiving, order filling, and shipping.

c.) Returned goods processing.

d.) Damages and outdates.

e.) Recalls

f.) Stock rotation

g.) Record keeping

h.) Security

i.) Applicable policies and procedures

6.) Facility managers and supervisors must have working knowledge of all relevant PDMA requirements.

7.) Management and supervisory personnel shall complete and maintain a written description of their duties and a summary of their qualifications **(Form FA01.00)**.

EA01.00

PRESCRIPTION DRUG MARKETING ACT (PDMA)

General Requirements

Employee Guide

PRESCRIPTION DRUG MARKETING ACT

EMPLOYEE GUIDELINES

The Prescription Drug Marketing Act (PDMA) amended the Federal Food, Drug, and Cosmetic Act to require State licensing of prescription drug wholesalers under federal guidelines established by the United States Food and Drug Administration. These guidelines set minimum standards for the storage, handling, and record-keeping of prescription human drugs. The purpose of these guidelines is to assure that the prescription drug products we distribute to our customers, who in turn distribute them to the end user, are safe and effective.

Cardinal Health, Inc., and your facility have developed operating policies and procedures to assure compliance with PDMA's requirements.

If you are not familiar with these policies and procedures or have any questions, comments, or concerns regarding the contents of these guidelines, please contact your Distribution Center Manager.

Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drug Records

The following are PDMA's minimum requirements for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records:

A. FACILITIES

All facilities at which prescription drugs are stored shall:

1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

3. Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

4. Be maintained in a clean and orderly condition; and

5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

B. SECURITY

1. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.

   a. Access from outside the premises shall be kept to a minimum and be well-controlled.

   b. The outside perimeter of the premises shall be well-lighted.

   c. Entry into areas where prescription drugs are held shall be limited to authorized personnel.

2. All facilities shall be equipped with an alarm system to detect entry after hours.

3. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.

C. STORAGE

All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs.

1. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature. Controlled room temperature is defined as 20 to 25 degrees Celsius, or 68 to 77 degrees Fahrenheit. The humidity limit is 76 percent.

2. Temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs.

D. EXAMINATION OF MATERIALS

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. Products with obvious defects or problems should be refused and returned to the supplier or, if received, placed in quarantine pending return to the supplier or destruction.

2. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions. Order fillers and quality control personnel must inspect product for damage, dating, and packaging as well as order accuracy. Delivery drivers must inspect product for damage.

3. The oldest approved stock of a prescription drug product shall be distributed first.

E. RETURNED, DAMAGED, AND OUTDATED PRESCRIPTION DRUGS

1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.

2. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

3. If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, or purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been

held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping. FDA has stated that returns may be put back into stock if the following two conditions are met:

- A thorough visual inspection of the condition of the product is conducted and does not cast doubt on the drug's integrity.
- Documentation from the customer, assuring that the product was stored, handled, and shipped properly, is received as part of the return process.

F. RECORDKEEPING

1. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.
2. Inventories and records shall be maintained for three years following disposition of the drugs.

G. GUIDELINES FOR REFRIGERATED PRODUCTS

1. RECEIVING

All product received in refrigerated containers must be visually examined to ensure the product is suitable for sale. Ensure that the product is not warm or frozen. If the product is frozen or warm, quarantine and contact the vendor for further instructions. After documenting receipt of the product, immediately transfer the coolers to the refrigerator for storage.

2. SHIPPING

All products that are refrigerated must be shipped in Styrofoam coolers with frozen ice packs or in a tote with Styrofoam inserts and frozen ice packs or gel packs.

3. DELIVERY

Refrigerated products must be opened by the pharmacy and verification made that product is still cold and not frozen or warm. If product integrity has been altered, the refrigerated order must be refused or Cardinal Health Customer Service must be contacted for further instructions.

4. REFRIGERATED RETURNS

Refrigerated products returned by customers must be shipped back to the distribution center in refrigerated containers. Cardinal Health facilities shall send refrigerated container(s) as well as ice packs to customers desiring to return refrigerated prescription drugs. Cardinal Health returns clerks must verify product integrity once delivered to Cardinal Health returns department. (See item number one (1) above.) No refrigerated returns shall be accepted on Fridays. An ongoing assurance must be received from the customer.

RECEIPT OF PRESCRIPTION DRUG MARKETING ACT (PDMA) EMPLOYEE GUIDE

I HEREBY ACKNOWLEDGE RECEIPT OF THE PDMA EMPLOYEE GUIDE.

I ALSO ACKNOWLEDGE THAT I HAVE READ THE PDMA GUIDE AND UNDERSTAND THE ACT'S REQUIREMENTS AS THEY APPLY TO MY SPECIFIC JOB FUNCTION.

EMPLOYEE SIGNATURE: _____

DATE: _____

WITNESS: _____

DATE: _____

DATE

NAME TITLE

DUTIES AND RESPONSIBILITIES:

QUALIFICATIONS*

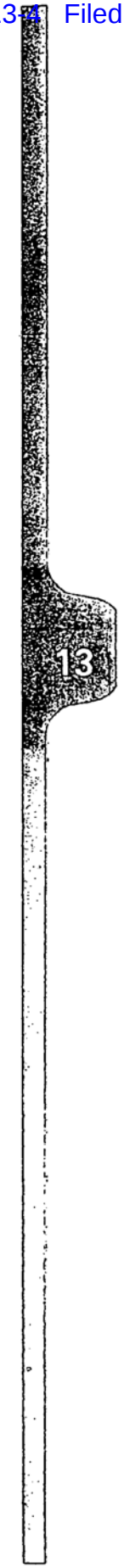
EDUCATION:

	Name and Location of School	Years Attended From	To	Diploma or Degree Received	Major Course of Study
High School					
College					
Graduate School					

EMPLOYMENT EXPERIENCE:

	Dates of Employment From	To	Position: Duties and Responsibilities
1. Employer Name and Address			
2. Employer Name and Address			
3. Employer Name and Address			

* A current resume may be attached in lieu of completing this section.



CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA02.00

TITLE: Security Procedures

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA02.00**
TITLE: Security Procedures	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. security requirements.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Security of the facility and warehouse shall be the responsibility of the Facility Manager or his designee. The facility shall:

a.) Be secure from unauthorized entry.

b.) Have the perimeter of the premises well-lighted.

c.) Be equipped with an alarm system to detect entry after hours.

d.) Be equipped with a security system that will provide suitable protection against theft and diversion.

2.) All non-employees entering the facility must be identified as a visitor. Visitors shall:

a.) Register with the receptionist.

b.) Be issued a visitor's badge.

c.) Be escorted during their visit by a Cardinal Health employee.

i.) Outside contractors shall be monitored through a cooperative effort of division management, supervisory personnel and full-time employees.

3.) The facility must limit access to the general warehouse to only those employees who have a full-time work assignment that reasonably requires their presence in the warehouse.

a.) The facility shall maintain a list of employees authorized to have routine warehouse access.

Cardinal Health

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA03.00

TITLE: Record Keeping

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ **Date:** 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

Cardinal Health **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA03.00**
TITLE: Record Keeping	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for records pertaining to the inventories, receipt, distribution and disposition of prescription drug products.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility shall establish and maintain records of all transactions regarding the receipt, distribution or other disposition of prescription drugs. The records shall include:

   a.) The source of the drugs, including the name and principal address of the seller or transferor, and the address from which the drugs were shipped.

   b.) The identity and quantity of the drugs received, distributed, or disposed of.

   c.) The dates of receipt, distribution, or other disposition of the drugs.

2.) Inventories and records shall be made available for inspection and photocopying by authorized Federal, State, or local law enforcement agency officials for a period of 3 years or longer if mandated by state record keeping requirements. (Exhibit EA03.00)

   a.) Records kept at the facility or those that can immediately be retrieved by computer or other electronic means shall be made readily available for authorized inspections during the retention period.

   b.) Records kept at a central location apart from the facility shall be available for authorized inspections within 2 working days of the request by authorized officials.

EA03.00

RECORD RETENTION

All records related to the receipt, sale, delivery, inventory, disposal, or storage of prescription drug must be retained for a period of three years.

The following state record retention requirements exceed this 3 year requirement:

State	Retention Period	Cite
Hawaii	5 years	Administrative Rules Title 16 Chapter 95 S16-95-96(c)
Kansas	5 years	Pharmacy Act Article 14 S68-14-7(f)(2)
New York	5 years	Pharmacy Regulation Part 63 S63.6(c)(5)

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA04.00**
TITLE: Prescription Drug Inspection	**ISSUE DATE:** 6-5-2006 **PAGE:** 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ **Date:** 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

Cardinal Health **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA04.00**
TITLE: Prescription Drug Inspection	**ISSUE DATE:** **PAGE: 2 of 2**

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for prescription drug inspections.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility shall examine all prescription drug products for condition and salability during the following processes:

a.) Receiving

b.) Order filling

c.) Delivery

d.) Returns

2.) The facility shall immediately quarantine any product deemed unfit for distribution until the product is destroyed or returned to the supplier.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA05.00

TITLE: Receiving Prescription Drugs

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA05.00**
TITLE: Receiving Prescription Drugs	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for receiving prescription drugs.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Upon receipt of prescription drugs, receiving personnel shall visually inspect shipping container for damage or other physical condition that would suggest possible contamination or other damage to the contents.

   a.) Merchandise that appears damaged or otherwise suspect must be immediately reported to Inventory Control to determine whether or not to accept the shipment.

2.) Upon accepting shipment, receiving personnel shall:

   a.) Locate electronic purchase order that corresponds with the shipment.

   b.) Open all repacked merchandise cartons and systematically sort the product.

   c.) Verify each item to the description on the electronic purchase order paying particular attention to:

      i.) Unit of measure based on the way we sell versus the way the vendor ships.

      ii.) Exact form of product (i.e. tablets, capsules, liquid, description, size, strength, etc.)

      iii.) NDC or UPC

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA05.00**
TITLE: Receiving Prescription Drugs	**ISSUE DATE:**
	PAGE: 3 of 3

3.) Product received in refrigerated containers must be visually examined to ensure product is suitable for sale.

a.) If product is warm or frozen, quarantine and contact vendor for further instructions.

b.) After documenting receipt, coolers shall immediately be transferred to the refrigerator receiving area.

4.) All discrepant items must be segregated until disposition is determined.

5.) Expiration dates of all items must be checked according to company policy.

6.) Receiving personnel shall record the actual quantity received.

7.) All missing and quantity changed items shall be compared to the packing list.

8.) Inventory Control shall be informed of all overages and shortages.

9.) All controlled and/or narcotic items must be promptly delivered to the vault or cage area.

10.) All refrigerated and frozen product must be promptly delivered to appropriate storage areas.

11.) All receiving paperwork shall be forwarded to appropriate personnel.

a.) Receiving records must be retained on file per **SOP FDA03.00**.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA06.00

TITLE: Replenishing and Restocking Static Shelves and Flow Racks

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA06.00

TITLE: Replenishing and Restocking Static Shelves and Flow Racks

ISSUE DATE:

PAGE: 2 of 2

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for replenishing and restocking.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Merchandise shall be routed to the appropriate zone.

2.) Facility personnel must determine that the merchandise is placed in the proper location.

3.) Product shall be compared with shelf label to ensure description and size are correct.

a.) Stock merchandise according to the unit of sale (i.e. each, 6's, 12's etc.)

4.) Product shall be inspected for damage.

a.) If product is damaged, contact a supervisor for further instructions.

5.) Short-dated merchandise shall be placed in front of longer-dated merchandise on shelf or flow rack.

6.) All product locations shall be maintained in a clean and orderly fashion.

7.) Merchandise that does not fit in the primary location shall be transferred to a secondary location.

8.) All trash (i.e. empty cartons, cellophane wrap, etc.) shall be disposed of properly.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:
FDA07.00

TITLE: Prescription Drug Storage

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA07.00**
TITLE: Prescription Drug Storage	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for storage of prescription drugs.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility shall store prescription drugs at appropriate temperatures and under appropriate conditions as required by:

   a.) Product label

   b.) Current edition of an official compendium (e.g. United States Pharmacopoeia/National Formulary (USP/NF)).

2.) If no special storage requirements are established for a prescription drug, the facility shall store such product at controlled room temperature.

3.) The facility must record temperature and humidity levels in all drug storage areas using a continual monitoring device unit.

   a.) The units shall be mounted in a centrally located section of the warehouse at a lower level.

   b.) The units must be calibrated on an annual basis and calibration records shall be maintained.

   c.) A spare monitor shall be obtained for use when other units are sent out for calibration or repair.

4.) The facility must retain temperature and humidity records per **SOP FDA03.00**. Records shall be maintained on:

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA07.00**
TITLE: Prescription Drug Storage	**ISSUE DATE:** **PAGE:** 3 of 3

a.) Diskette; or

b.) A Temperature Control Log **(Form FA07.00)**

5.) Any prescription drug that is suspected of being stored at improper temperatures, including freezing, shall be quarantined until disposition of the drug is determined.

a.) A separate area shall be established within the return goods area, the cage, the vault, the refrigerator and the freezer for prescription drugs under quarantine.

Reference: Exhibit EA07.00

CardinalHealth

FA07.00

Temperature control log

Division location _____ For the month of _____

Monitor Location _____ # of monitors at division_____

Date	Temperature		Humidity		Initial
	Maximum	Minimum	Maximum	Minimum	
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					

_____

Average monthly temperature

_____ _____

Mean kinetic temperature Division Manager's signature

Use one log per monitor. Log daily at approximately the same time each day.
*Please provide if average monthly temperature is greater than 77.

White - Division Yellow - Corporate Compliance

DUB 1303
Rev 10/04

FOIA Confidential Treatment Requested By Cardinal

CAH 022328

Temperature/Humidity Requirements

Controlled Room Temperature

Controlled room temperature is defined as 20-25 degrees Celsius or 68-77 degrees Fahrenheit with a mean kinetic temperature calculated to be no more than 25 degrees Celsius (77 degrees Fahrenheit) with allowable excursions between 15 to 30 degrees Celsius (59 to 86 degrees Fahrenheit). This mean kinetic temperature is calculated from average storage temperatures recorded over a twelve-month period, from a minimum of twelve equally spaced recorded average storage temperature observations.

At the end of a twelve-month period, if any of those twelve average storage temperatures show excursions beyond 25 degrees Celsius (77 degrees Fahrenheit), then the kinetic mean must be calculated on the twelve average storage temperatures. The formula to perform this calculation has been provided on disk from Corporate Compliance.

The humidity limit is 76 percent. There is nothing in the USP or on product labels that denotes specific humidity requirements. Manufacturers, however, report that product is usually tested for stability at this level.

Refrigerated Products

Storage requirements apply to refrigerated product and temperature and humidity must also be documented for these storage areas. Storage temperatures for refrigerated product must be between 2 and 8 degrees Celsius, or 35 to 46 degrees Fahrenheit. A temperature/humidity recorder is appropriate for walk-in units. Other types of refrigeration units must be monitored and recorded manually. There is nothing in federal or state laws or regulations which addresses frequency of readings when keeping manual records but, once per shift would be a reasonable policy for assuring the product is stored properly.

Recording Temperatures and Humidity

Appropriate electromechanical or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.

The temperature of the drug storage area must be recorded with a continual monitoring device. Manual temperature recording equipment is not acceptable except as noted above for refrigerated product.

These units must be mounted in a centrally located section of the warehouse at a lower level that allows them to be accessible, yet protects them from damage.

Temperature monitoring systems must be calibrated on an annual basis and records must be maintained. A spare monitor must be obtained for use when other units are sent out for calibration or repair.

EA07.00

Controlled Room Temperature Requirements

Questions & Answers

1. Which federal laws and regulations impose temperature control requirements on drug wholesalers?

The Prescription Drug Marketing Act of 1987 (PDMA) was signed into law on April 22, 1988 (Pub. L. 100-293). Guidelines for state licensure of wholesale drug distributors, which were mandated by the Act, were published on September 14, 1990 (55 FR 38012) and went into effect two years later. The guidelines contain minimum requirements for storage and handling of prescription drugs, including warehouse temperature control requirements.

The guidelines in 21 CFR 205.50(c) direct wholesalers to store prescription drugs at "appropriate temperatures" in accordance with product labeling or the requirements in "the current edition of an official compendium." Drugs that do not have labeled or published temperature control requirements are to be held at "controlled room temperature" as defined in an official compendium.

FDA considers the United States Pharmacopeia (USP) an "official compendium" for the purposes of PDMA.

2. What was the previous USP definition of "controlled room temperature?"

Until last year, USP defined controlled room temperature as a temperature maintained between 15 and 30 degrees Celsius (59 to 86 degrees Fahrenheit). Temperature data could be gathered using manual or electronic temperature recording equipment.

3. What is the new USP definition of "controlled room temperature?"

In its September/October 1993 edition of Pharmacopeial Forum, USP changed the definition of controlled room temperature. The new definition is a temperature between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit) that results in a mean kinetic temperature (MKT) calculated to be not more than 25 degrees Celsius (77 degrees Fahrenheit), with allowable excursions between 15 and 30 degrees Celsius (59 and 86 degrees Fahrenheit).

4. Why did USP change the "controlled room temperature" definition?

The Food and Drug Administration (FDA) and other national and international groups are participating in an ongoing effort to harmonize international regulatory requirements for pharmaceutical testing and development. The new controlled room temperature definition is intended to bring U.S. temperature storage requirements in line with the temperatures used internationally for long-term stability testing. Stability testing to support controlled room temperature storage statements on pharmaceuticals products is conducted internationally at 25 degrees Celsius (77 degrees Fahrenheit).

5. What is mean kinetic temperature (MKT)?

The degree a pharmaceutical product degrades (breaks down) varies as temperature changes during a storage period. MKT is used to measure the degradation of the product at various temperatures. Specifically, MKT is the temperature at which the total amount of degradation over a particular period is equal to the sum of the individual degradations that occur at various temperatures.

6. What does the change in the definition of "controlled room temperature" mean to drug wholesaler?

Prescription drugs that are stored at controlled room temperature must now be stored between 20 and 25 degrees Celsius (68 and 77 degrees Fahrenheit. Temperature excursions between 15 and 30 degrees Celsius (59 and 86 degrees Fahrenheit) are allowed under the new definition.

Wholesalers must take daily temperature readings and, based on those readings, compute an average temperature for each month. If the average temperature for the current month or any of the previous 11 months exceeds 25 degrees Celsius (77 degrees Fahrenheit), you must compute the MKT for that 12 month period.

The MKT can be calculated automatically simply by entering your temperature data on the diskette provided by Corporate Compliance. The MKT will be continually calculated as you add new temperature data, based on the current month and the previous 11 months. This gives you a "rolling" MKT, which is always up to date.

7. What if the monthly average temperature or MKT exceeds 25 degrees Celsius (77 degrees Fahrenheit)?

FDA has stated that wholesalers should make sure "procedures are implemented to correct storage temperature conditions when the average monthly temperature exceeds 25 degrees C". Similar actions is required if you MKT is above 25 degrees Celsius. The agency has not provided any guidance on what such corrective action should or must entail, or what actions the agency might take against wholesalers who violate the 25 degrees Celsius (77 degrees Fahrenheit) limit.

Wholesalers who find that their monthly average temperature exceeds the 25 degrees Celsius (77 degrees Fahrenheit) limit should lower their warehouse temperature to a level that ensures that the next month's average is at or below the limit. When taking this type of corrective action, wholesalers should try to compensate for previous high monthly averages so that the MKT does not rise above 25 degrees Celsius (77 degrees Fahrenheit).

8. Which drugs must be stored at controlled room temperature?

Prescription drugs that are labeled "store at controlled room temperature" must be stored in accordance with the new USP "controlled room temperature" definition. Prescription drugs that have no specific

labeled or published temperature storage requirements must also be stored in accordance with the new definition.

Some prescription drugs currently bear more specific temperature labeling in accordance with the old temperature control requirements. For example, wholesalers will probably find products in the warehouse with labels bearing storage instructions such as "store at up to 86 degrees Fahrenheit" or "store at controlled room temperature, up to 86 degrees Fahrenheit."

For now, you are in compliance if you store these products at 86 degrees Fahrenheit. However, manufacturers will be changing the labeling on these products in accordance with international harmonization efforts to reflect an upper limit of 25 degrees Celsius (77 degrees Fahrenheit), so you may wish to begin storing these products according to the new standard now to ensure compliance. Remember that these products are subject to the same temperature monitoring requirements as those stored under the new "controlled room temperature" definition.

9. How many temperature readings are required?

FDA and USP currently disagree on how frequently temperature readings should be taken. FDA believes that two temperature data points should be required for each day, while USP has told us that less frequent data collection is adequate to demonstrate compliance.

The diskette from Corporate Compliance requires you to input two data points each day, in accordance with the current FDA interpretation. In the event that FDA and USP eventually decide on a different frequency, an updated diskette will be provided.

10. Are their any special requirements regarding temperature monitoring equipment?

Yes. Previously temperature data could be gathered using either manual or electronic temperature recording equipment. Under the new requirements, according to FDA, "the temperature of the drug storage area must be recorded with either a continual monitoring device or a high/low thermometer..." Manual temperature recording equipment is no longer acceptable.

FDA has not provided any specific guidance in PDMA on how many temperature monitoring devices must be used in the warehouse or where they should be placed. Wholesalers should use their best professional judgment in determining the number and placement of these devices.

11. What about recordkeeping?

Wholesalers must keep careful records of their temperature data. Separate records must be kept for each temperature monitoring device in the warehouse. Records may be kept at a central location as long as they are readily available for inspection upon the request of an authorized official.

The current PDMA regulation instruct wholesalers to retain records for three (3) years, so you should keep your temperature records for a minimum of three years.

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO: FDA08.00

TITLE: Prescription Drug Inventory

ISSUE DATE: 6-15-2006

PAGE: 1 of 4

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA08.00**
TITLE: Prescription Drug Inventory	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for Prescription Drug Inventories.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each distribution center will conduct a complete prescription drug inventory on a semi-annual basis.

2.) Prior to physical inventory, the facility must contact Information Services and request a printout of count sheets with on-hand quantities suppressed.

3.) On the day prior to physical inventory, the facility must notify Credit and Receiving Departments not to enter any transactions after close of business that day until 12 noon on the day inventory is taken.

4.) Once all orders have been picked on the day of inventory, the facility shall conduct physical inventory of all prescription items, posting counts on count sheets.

5.) On the day of inventory, after prior day's business has been processed, the facility must contact Information Services and request a current printout listing prescription items with on-hand quantities included.

6.) The facility must compare results of the inventory with the current on-hand balance of items.

a.) Recount out-of-balance non-controlled prescription drug items according to facility dollar variance policy. This must be conducted prior to the picking of any orders. All controlled substance items in variance must be recounted.

b.) Note out-of-balance items on the second printout of count sheet.

7.) The facility must request Transaction Reports for all out-of-balance items.

8.) The facility shall recount each out-of-balance item.

a.) Obtain inventory quantity for items in question from the system.

b.) Compare the system quantity to the recounted quantity and subtract to find the difference.

c.) Compare the difference to the quantity shown on the Transaction Reports.

i.) If the quantities are the same, go to the next step.

ii.) If the quantities do not match, recount out-of-balance items.

9.) The facility shall review the Transaction Reports for each out-of-balance item and attempt to determine the reason for the variance.

a.) If an error causing an out-of-balance is detected, make the appropriate adjustments to the system to correct the quantity.

10.) If all research has been exhausted and an out-of-balance condition still exists, the facility shall determine the item to be lost or stolen and inventory shall be adjusted accordingly.

Note: The reporting of inventory variances to the appropriate state and federal agencies must be carefully evaluated. Variances, which are the result of record keeping or order filling errors, need not be reported. Actual discrepancies, which are the result of a theft or significant loss, must be reported.

11.) All count sheets and reconciliation paperwork must be retained on file at the facility in accordance with SOP FDA 03.00.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:
FDA09.00

TITLE: Order Filling

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06
Stephen J Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA09.00**
TITLE: Order Filling	**ISSUE DATE:**
	PAGE: 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for the filling of prescription drug orders.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Pick documents shall be created for all customer orders and printed by route and stop number.

2.) Orders must be filled from the pick document.

3.) Order selectors must visually examine all product for salability. Conditions which affect salability include:

a.) Damage to packaging.

b.) Obliteration of labeling.

c.) Shelf life dating.

d.) Compatibility to current manufacturer packaging.

e.) Destruction of factory seal.

f.) Conditions under which the product has been stored.

i.) Any product suspected of being stored or shipped under improper conditions, including freezing, shall be immediately quarantined and the manufacturer must be contacted to determine the ultimate disposition of the product.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA09.00**
TITLE: Order Filling	**ISSUE DATE:**
	PAGE: 3 of 3

4.) Saleable products shall be placed in the appropriate shipping container.

a.) Refrigerated products must be shipped in either:

i.) Styrofoam coolers with frozen ice packs.

ii.) Tote with Styrofoam inserts and frozen ice packs or gel packs.

5.) Non-saleable products must be:

a.) Written up on an Outdated and/or Damages Form.

b.) Transferred to the returned goods area for quarantine pending destruction or return to supplier.

6.) Upon completion of the order, the tote and paperwork shall be transferred to Quality Control for verification or correction. **(Refer to SOP FDA10.00 Quality Control)**

7.) Completed orders shall be:

a.) Transferred to the shipping dock.

b.) Staged by route number and stop.

c.) Manifested.

d.) Loaded onto delivery vehicles.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA10.00

TITLE: Quality Control

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA10.00**
TITLE: Quality Control	**ISSUE DATE:**
	PAGE: 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for quality control and to ensure that orders shipped to customers are accurate and in good condition.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Quality Control must scan tote and product at Quality Control Workstation, checking for:

a.) Size.

b.) Strength.

c.) Unit of measure.

d.) NDC

e.) Dosage form

f.) Condition of merchandise.

i.) If the product is not sellable because of damage or an incomplete selling unit, complete a breakage report and remove product from stock.

ii.) Replace unsellable product in customer's order.

g.) Incorrect item:

i.) If an incorrect item is found, replace the incorrect item in customer's order.

h.) Quantity error:

i.) If an overage or shortage is found, correct the error.

2.) Upon completion of the order, Quality Control shall forward the order to Shipping.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA10.00**
TITLE: Quality Control	**ISSUE DATE:**
	PAGE: 3 of 3

3.) All quality control paperwork must be delivered to personnel designated by facility management.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA11.00

TITLE: Distribution and Delivery

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA11.00**
TITLE: Distribution and Delivery	**ISSUE DATE:**
	PAGE: 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for distribution and delivery of prescription drug product.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Deliveries shall be made through entrance locations approved by the customer.

2.) The driver shall bring customer invoices for each order delivered and the appropriate shipping manifest for the delivery.

3.) If all product is present and in good condition, the driver shall have the customer sign the manifest.

4.) If there is a shortage, the driver shall:

a.) Post correct quantity on the manifest and initial the change.

b.) Secure the customer signature for product delivered.

c.) Instruct the customer to contact Customer Service for resolution.

d.) Notify the transportation or depot manager.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA11.00**
TITLE: Distribution and Delivery	**ISSUE DATE:** **PAGE:** 3 of 3

5.) If product is damaged, the driver shall:

a.) Notify the transportation or depot manager who will, in turn, notify designated facility personnel.

b.) Collect, secure and seal damaged product in a recovery bag.

c.) Secure customer signature for product delivered.

(Note: Damaged product shall include all product that comes in contact with liquid from a broken bottle and any product stored or shipped under improper temperature conditions including freezing.)

6.) The driver shall request, from the customer:

a.) DEA 222 forms in sealed envelopes

b.) Payments

c.) Other communication intended for return to Cardinal Health.

7.) The driver shall collect all returnable totes from the customer.

8.) The driver shall pick up customer returned goods, sign the credit request form or pickup slip and leave a copy with the customer.

9.) The driver shall return all paperwork and any product to the transportation or depot manager at the end of day.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA12.00

TITLE: Return Goods Processing

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA12.00**
TITLE: Return Goods Processing	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with DEA, State and Cardinal Health, Inc. requirements for processing returned goods.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each customer must sign an Ongoing Assurance Form (**Form FA12.00**) as a prerequisite to participation in a returned goods program.

2.) The facility must verify each return authorization is signed by the customer attesting to proper storage and handling of the product while it was under their control. If the return authorization is not signed, the return shall not be processed until a signature is obtained. If a signature cannot be obtained, product must be transferred to the morgue area and quarantined pending destruction or return to supplier. (**Exhibit EA12.00**)

3.) The facility must match returned goods to the credit request form and/or pickup slip, noting the following:

   a.) Product listed but not received.

   b.) Product not listed but received.

4.) If a product is received from an unknown source, label it as "Customer Unknown".

   a.) All "Customer Unknown" product must be transferred to the morgue area and quarantined pending destruction or return to supplier.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA12.00**
TITLE: Return Goods Processing	**ISSUE DATE:**
	PAGE: 3 of 3

5.) The facility must visually evaluate product for saleability. Conditions which affect saleability include:

a.) Damage to packaging.

b.) Obliteration of labeling.

c.) Insufficient shelf-life dating.

d.) Compatibility to standard manufacturer packaging.

e.) Damage to factory seal.

f.) Conditions under which the product has been stored and shipped.

i.) Refrigerated products received from the customer must be packed in styrofoam coolers or styrofoam lined totes with suitable ice packs or gel packs.

ii.) Product that is suspected of being stored or shipped under improper temperature or humidity conditions shall be immediately quarantined from product suitable for sale.

6.) The facility shall return all saleable merchandise to warehouse locations, placing longer-dated merchandise behind shorter-dated merchandise.

7.) The facility shall transfer all non-saleable merchandise to the morgue area for quarantine pending destruction or return to supplier.

8.) The facility shall process customer credit according to applicable Cardinal Health Returned Goods Policy.

FA12.00

CARDINAL HEALTH RETURNED GOODS AUTHORIZATION ONGOING ASSURANCE

The undersigned customer ("Customer") of Cardinal Health ("Wholesaler") hereby agrees that this document is being delivered to confirm Customer's compliance with applicable Federal, state, and local laws/guidelines concerning returned goods and shall apply to all returns by Customer to Wholesaler from time to time and shall supersede any inconsistent provisions which may be contained in any credit request, purchase order, or other documents pertaining to the supply relationship between Customer and Wholesaler.

1. Customer represents, warrants, and guarantees to Wholesaler that: (a) each such return shall be made only to the specific Wholesaler from which the item was originally purchased; (b) each such return shall be accompanied by Wholesaler's credit request form (the "Return Form"), which shall specify both Customer's and Wholesaler's name and address, the date of the return, the quantity and description of the product returned, and such information as may reasonably be requested on Wholesaler's Return Form; (c) Customer shall retain a copy of each Return Form and related credit memo and make such documentation available to the manufacturer and to authorized Federal, state, and local law enforcement officers upon request; (d) the credit claimed or accepted by Customer for any such return shall not exceed the original purchase price paid to Wholesaler: and (e) all merchandise returned to Wholesaler has been stored, handled, and shipped by Customer in accordance with all applicable Federal, state, and local laws, manufacturer guidelines, and good trade practices, and such merchandise has not been adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and meets all FDA, state, and other applicable requirements and guidelines.

2. Customer shall indemnify and defend Wholesaler against and from any expense, claim, liability, or penalty (including reasonable legal fees) arising from any failure of Customer to properly comply with provisions specified in this document.

3. The term "Wholesaler" as used in this document shall include any subsidiary or affiliate of Cardinal Health, Inc., which are collectively or individually referred to as Cardinal Health.

_____
Customer's Name (Print)

Date:_____ _____
Authorized Signature Title

FOIA Confidential Treatment Requested By Cardinal

CAH 022353

CONFIDENTIAL

CAH_MDL_PRIORPROD_DEA07_01188659

P-14290 _ 00716

EA12.00

CREDIT / RETURN AUTHORIZATION

CARDINAL DISTRIBUTION - AUBURN

a Cardinal Health company

411659
APRIA HLTHCRE GRP INC. REDMOND
14935 NE 87TH
REDMOND, WA 98052

411659
APRIA HLTHCRE GRP INC. REDMOND
14935 NE 87TH
REDMOND, WA 98052

RETURN AUTHORIZATION NO. 309768

ROUTE/STOP 666/ 39 CONF #

ACCOUNT NO.	SALESPERSON	PAGE NO.		
411659	944	309768		1

DATE REQUESTED 12/18/2002 129468~186

CUSTOMER ITEM #	QTY	U.O.M.	MFG. ITEM #	DESCRIPTION	RSN	CDD	INVOICE # / DATE
1 332718	1	CT	00074678002	LORAZEPAM 2MG/ML 10X10ML C4 CONTROLL		32	3649825 10/04/2002
				CONTL-REFG			
				**** CONTROL ****			
				**** PICKUP ONLY--CREDIT TO FOLLOW ****			
				SIGNED CARDINAL DRIVER:			
				(DRIVER TO SIGN WHEN MERCHANDISE IS PICKED UP. DRIVER IS SIGNING FOR BULK PICKUP ONLY, INDIVIDUAL MERCHANDISE TO BE CHECKED IN AT CARDINAL WAREHOUSE.)			
				THE UNDERSIGNED CUSTOMER REPRESENTS, WARRANTS AND GUARANTEES TO CARDINAL HEALTH THAT ALL MERCHANDISE RETURNED TO CARDINAL HEALTH HAS BEEN STORED, HANDLED, AND SHIPPED BY CUSTOMER IN ACCORDANCE WITH MANUFACTURER GUIDELINES AND ALL APPLICABLE FEDERAL, STATE, AND LOCAL LAWS, INCLUDING THE PRESCRIPTION DRUG MARKETING ACT.			
				CUSTOMER SIGNATURE			
TOTAL:	1						

VOID

The Reizon Company

CH10300 7/96

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA13.00

TITLE: Identifying and Processing Damaged and/or Outdated Prescription Drug Product

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA13.00**
TITLE: Identifying and Processing Damaged and/or Outdated Prescription Drug Product	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for identifying, processing and adjusting inventory for damaged and outdated prescription drug product.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Each shift shall be responsible for properly completing a form for all damaged or outdated prescription drug product identified on that shift.

a.) Outdated merchandise shall be identified as:

i.) Expired product per the expiration date provided by the manufacturer.

ii.) Product determined outdated per company policy.

b.) Damaged product shall identified as:

i.) Damage to packaging.

ii.) Obliteration of labeling.

iii.) Compatibility to current manufacturer packaging.

iv.) Destruction of factory seal.

v.) Products stored under improper temperature conditions, including freezing.

2.) All product identified as damaged and/or outdated, along with the form, shall be promptly delivered to the morgue area for quarantine pending destruction or return to vendor.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA13.00**
TITLE: Identifying and Processing Damaged and/or Outdated Prescription Drug Product	**ISSUE DATE:** **PAGE:** 3 of 3

3.) Upon delivery to the morgue area, each item must be compared to the appropriate form used to document the damaged and/or outdated product, ensuring that descriptions and quantities are consistent with product received in the morgue area.

   a.) Changes shall be made on the form, when necessary, to accurately reflect product received and changes shall be initialed by the processor.

4.) Product shall be placed in the appropriate quarantine bin for final disposition.

5.) Completed forms must be forwarded to designated personnel.

6.) Designated personnel shall adjust the live and morgue inventories.

   a.) All adjustments must be reviewed for accuracy.

7.) Inventory adjustment paperwork must be maintained per **SOP FDA03.00**.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA14.00

ISSUE DATE: 6-15-2006

TITLE: Destruction of Merchandise

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

f.) Create a Debit Memo, which will adjust morgue inventory accordingly.

g.) Destroy merchandise in accordance with applicable Federal, State, and local requirements.

h.) Give original form and Debit Memo to Manufacturer Representative or broker.

i.) Forward a copy of form and Debit Memo to the Accounting Department.

j.) Retain file copies per **SOP FDA03.00**.

2.) When requesting authorization to destroy merchandise directly from the manufacturer, the facility shall:

a.) Follow Steps 1 (a) and 1 (b) as listed above.

b.) Send original copy of form to the Manufacturer and await authorization to destroy.

c.) File a copy of the form in pending file.

3.) Upon receipt of authorization to destroy, the facility shall:

a.) Match the authorization to copy of form in pending file and staple together.

b.) Obtain signature of Director of Operations or his designee.

c.) Move merchandise to pending vendor status.

d.) Create a Debit Memo, which will adjust morgue inventory accordingly.

e.) Destroy merchandise using an authorized reverse distributor in accordance with applicable Federal, State, and local requirements.

f.) Forward forms to the Accounting Department.

g.) Retain a file copy per **SOP FDA03.00**.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA14.00**
TITLE: Destruction of Merchandise	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for destruction of merchandise, to include containers, labels and packaging, and to obtain credit for destroyed merchandise.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) When a Manufacturer Representative or broker comes to the facility to authorize destruction of merchandise, the facility shall:

a.) Complete one of the following forms:

i.) The Manufacturer's Return/Destroy Authorization Form.

ii.) A Vendor Return Request Form.

b.) Ensure the following information is included on the form:

i.) Item number

ii.) UPC/NDC number

iii.) Quantity

iv.) Unit of measure

v.) Description/Lot number

vi.) The word "destroyed" and method of destruction.

c.) Obtain signature of authorizing Manufacturer Representative or broker.

d.) Obtain signature of Director of Operations or his designee.

e.) Move merchandise to pending vendor status.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA15.00

TITLE: Returning Merchandise to the Manufacturer

ISSUE DATE: 6-5-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA15.00**
TITLE: Returning Merchandise to the Manufacturer	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for returning merchandise to Manufacturers.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) When a Manufacturer Representative or broker comes to the facility to authorize return of merchandise, the facility shall:

a.) Complete one of the following forms:

i.) The Manufacturer's Return/Destroy Authorization Form.

ii.) A Vendor Return Request Form.

b.) Ensure the following information is included on the form:

i.) Item number

ii.) UPC/NDC number

iii.) Quantity

iv.) Unit of measure

v.) Description/Lot number.

c.) Obtain signature of authorizing Manufacturer Representative or broker.

d.) Move merchandise to pending vendor status.

e.) Create a Debit Memo, which will adjust morgue inventory accordingly.

f.) Ship merchandise to manufacturer along with original copy of forms.

g.) Forward copies of forms to the Accounting Department.

h.) Retain file copies per **SOP FDA03.00**.

2.) When requesting authorization to return merchandise directly to the manufacturer, the facility shall:

a.) Follow Steps 1 (a) and 1 (b) as listed above.

b.) Send original copy of form to the Manufacturer and await return authorization.

c.) File a copy of the form in pending file.

3.) Upon receipt of return authorization, the facility shall:

a.) Match the authorization to copy of form in pending file and staple together.

b.) Move merchandise to pending vendor status.

c.) Create a Debit Memo, which will adjust morgue inventory accordingly.

d.) Ship merchandise to manufacturer along with original copies of return authorization and Debit Memo.

e.) Forward forms to the Accounting Department.

f.) Retain a file copy per **SOP FDA03.00**.

CardinalHealth

CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA16.00

TITLE: In-House Lost, Stolen, and Damaged Product

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-2006

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA16.00**
TITLE: In-House Lost, Stolen, and Damaged Product	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for the handling, investigation, and documentation of in-house lost, stolen, or damaged prescription drug products, including products stored under improper temperature conditions.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) If a product is damaged during the receiving, warehousing, or order selection process, the following procedures must be followed:

a.) The employee having first hand knowledge of the damage shall notify his/her supervisor.

b.) The supervisor shall refer to the material safety data sheet (MSDS) to determine if the product is hazardous and for proper clean-up and disposal instructions.

i.) If the product is hazardous, collect, secure and seal damaged product according to the instructions on the MSDS.

ii.) If the product is not hazardous, collect, secure and seal damaged product in a plastic bag.

c.) Damaged product shall be transferred to the designated personnel who shall:

i.) Place damaged product in the morgue quarantine area pending destruction or return to the supplier.

ii.) Adjust inventory accordingly.

2.) If a shortage is revealed during an inventory, refer to **SOP FDA08.00 Prescription Drug Inventory.**

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA16.01

TITLE: In-Transit Lost, Stolen, and Damaged Product

ISSUE DATE: 6-15-2006

PAGE: 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA16.01**
TITLE: In-Transit Lost, Stolen, and Damaged Product	**ISSUE DATE:** **PAGE:** 2 of 3

PURPOSE: To comply with FDA, State and Cardinal Health, Inc. requirements for the handling, investigation, and documentation of in-transit lost, stolen, or damaged prescription drug products, including products stored or shipped under improper temperature conditions.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) If product is damaged in the delivery process, the following procedures must be followed:

a.) The driver shall:

i.) Notify the transportation or depot manager.

ii.) Collect, secure, and seal damaged product in a recovery bag.

iii.) Return the bag to the transportation or depot manager.

b.) The transportation or depot manager shall:

i.) Notify designated personnel at the Cardinal Health facility.

ii.) Return the bag, containing the damaged product, to designated personnel at the Cardinal Health facility.

c.) The designated personnel shall:

i.) Place the product in the appropriate morgue quarantine area pending destruction or return to the supplier.

ii.) Adjust inventory accordingly.

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA16.01**
TITLE: In-Transit Lost, Stolen, and Damaged Product	**ISSUE DATE:** **PAGE:** 3 of 3

2.) If product is lost or stolen in the delivery process, the following procedures must be followed:

a.) The driver shall:

i.) Immediately notify the transportation or depot manager.

ii.) Provide all information pertaining to the loss or theft.

iii.) Cooperate in the follow-up investigation with by Cardinal Health and/or State and Federal authorities.

b.) The transportation or depot manager shall immediately notify designated personnel at the Cardinal Health facility.

NOTE: A DEA Form 106 must be completed for all in-transit losses and/or stolen controlled substance products. Refer to SOP DEA 04-00. Significant in-transit losses and/or stolen prescription drug product must be reported to the appropriate state agency.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA17.00

TITLE: Recalls

ISSUE DATE: 6-5-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA17.00**
TITLE: Recalls	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with DEA, State and Cardinal Health, Inc. requirements for conducting a product recall.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Upon receiving notification of a manufacturer's product recall (**Exhibit EA17.00**), the Recall Coordinator shall immediately inform to the following personnel:

a.) Inventory control.

b.) Credit return.

c.) Customer Service.

2.) Inventory control personnel shall:

a.) Determine if recall product is in stock and, if found, immediately forward it to the morgue area for quarantine pending the return to the manufacturer;

b.) Record the results of the search and forward the information to the Recall Coordinator; and

c.) Identify and tag the product locations with a Recall Item Location Tag (**Exhibit EB17.00**) which includes the following information:

i.) Item number.

ii.) Lot number.

iii.) Date of recall.

3.) Recall Item Location Tags must be left in place for a period of six months from the date of the recall.

4.) If the manufacturer and/or FDA requests customer notification, the Recall Coordinator must take one of the following courses of action, depending on the class of the recall:

a.) Class I Recall:

i.) Create a customer list for the appropriate product and timeframe through the Information System Department. If timeframe has not been provided, one must be obtained from the recalling firm.

ii.) Promptly mail or fax each customer a notification (**Exhibits EC17.00, ED17.00**) identifying the recalled product, size, lot number and manufacturer's instructions for return.

iii.) The notification must include a means for the customer to sign and acknowledge receipt of the notification and to identify any recalled product on hand. Customers shall be requested to return the acknowledgement to the facility.

iv.) Send an invoice message notifying customers of the recall. Identify product, size, lot number and return instructions. Print the notice for a minimum of 3 business days.

b.) Class II Recall:

i.) Create a customer sales history listing for the appropriate product and timeframe through the Information System Department. If timeframe has not been provided, create a customer sales history for a timeframe equal to the current on-line history.

ii.) Mail or fax each customer a notification identifying the recalled product, size, lot number , reason for the recall and manufacturer's instructions for return.

c.) Class III Recall:

i.) Send an invoice message notifying customers of the recall. Identify product, size, lot number and return instructions. Print for a minimum of 3 business days.

d.) Unclassified recalls shall be handled as a Class II recall.

5.) The recall acknowledgement sheets for Class I and Class II recalls must be monitored. After 3 weeks, the customers who have not responded must be contacted by telephone or a second mailing.

6.) The Recall Coordinator shall:

a.) Notify the manufacturer of the inventory findings at the facility and recall actions taken using the form provided by the manufacturer.

b.) Retain records that include, when appropriate:

i.) The manufacturer's recall notice.

ii.) In-house inventory findings.

iii.) Copy of letter sent to the customer.

iv.) The recall acknowledgement receipts.

v.) The customer sales list.

vi.) The second request information.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA17.00**
TITLE: Recalls	**ISSUE DATE:**
	PAGE: 5 of 5

7.) Credit Return personnel shall:

a.) Monitor recalled product returns and insure they are quarantined pending return to the manufacturer.

8.) Recalls for which the FDA or manufacturer requests special notification procedures shall be handled individually using guidelines set forth by FDA or the manufacturer.

9.) Retain records per **SOP FDA03.00**.

ABBOTT

EA17.00

Hospital Products Division

Abbott Laboratories
200 Abbott Park Road
Abbott Park, Illinois 60064-6135

December 12, 2002

IMPORTANT DRUG RECALL
DEMEROL
(Meperidine HCl Injection USP)
50mg/mL (Carpuject)
NDC # 0074-1178-30
List No. 1178-30, Lot No. 94-645-3B

Dear Director of Pharmacy,

Abbott Laboratories is bringing to your immediate attention the recall of Demerol (Meperidine HCl USP), 50mg/mL (Carpuject), List No. 1178-30, Lot No. 94-645-3B. Abbott Laboratories initiated this voluntary recall after receiving one report of one 10-pack of Morphine, List No. 1762-30, over-wrapped with four 10-packs of Demerol, List No. 1178-30, Lot No. 94-645-3B, in a corrugate package labeled as Demerol.

Abbott Laboratories is initiating this recall as a precautionary measure with the full knowledge of the United States Food and Drug Administration. There have been no adverse heath events associated with this product mix. Abbott evaluated inventory of this lot still in its control and determined that it contained the correct product.

If you have existing inventory of the lot identified above please call Abbott Customer Service at 1-(800)-ABBOTT3 (1-(800)-222-6883) to arrange for return of the product. Abbott Customer Service will provide a Return Authorization Number and instructions to return the product. **Do not return product until Abbott Laboratories Customer Service has provided instructions to do so properly.**

We regret any inconvenience this action may cause you.

Sincerely,

for M. Van Trieste

Martin Van Trieste
Divisional Vice President
Quality Assurance
Hospital Products Division

FOIA Confidential Treatment Requested By Cardinal

CAH 022379

EB17.00

RECALL ITEM

PICK CODE

LOT#

DATE POSTED:
Tag must remain here 6 months

APR. 17. 2003 6:03PM NO. 6448 P. EC17.00

FROM

CARDINAL MISSISSIPPI, JACKSON
1240 GLUCKSTADT ROAD
MADISON, MS 39110

POSTAL INDICIA

*** URGENT PRODUCT RECALL *** 3/28/2002

on hand. If you have any questions please contact the Inventory Control Dept.

ITEM: 1314184 LEVOTHROID 25MCG 100 NDC#: 00456032001
MANUFACTUBER: FOREST
LOT NUMBERS: 120012

REASON FOR RECALL: ON NOVEMBER 18, 2001, FOREST PHARMACEUTICALS, INC. MANUFACTURER OF LEVOTHROID TABLETS, VOLUNTARILY RECALLED LEVOTHROID 25 MCG TABLETS, LOT#'S 120011 AND 120013, 100 COUNT BOTTLES, NDC#0456-0320-01. THIS RECALL IS NOW BEING EXTENDED TO LOT #120012, DUE TO LOW POTENCY PRIOR TO EXPIRATION.

Partial returns of non-controlled items must contain at least 25% of the original package in order for credit to be issued. Please fill in the above returned, sign, and RETURN THIS SHEET, WHETHER OR NOT YOU HAVE PRODUCT ON HAND. If you are returning product, PLEASE INCLUDE A CREDIT MEMO.

speedigram®

TO

Cust# 676523 IPO-105
PHARMACY CARE ASSOCIATES
132 MENDEL PARKWAY
MONTGOMERY, AL 36117

FOIA Confidential Treatment Requested By Cardinal

CAH 022381

CONFIDENTIAL

CAH_MDL_PRIORPROD_DEA07_01188687

P-14290 _ 00744

ED17.00

CardinalHealth

PHOENIX

RECALL CLASS: 2

To: Chief Pharmacist

Subject: Urgent Drug Recall

According to our records, you purchased an Item that has been recalled by the Manufacturer. Please examine your stock to determine if you have the following product on hand.

This recall is being made with the knowledge of the Food and Drug Administration

Reason For Recall : **Potential super-potency of some bottles.**

Item : 1) CIIN 2957439 NDC 9513601 ZYVOX 100MG/5ML 150ML DLTD

2) _____

Lot numbers : 11HKU 97HAH 82HHW 16HXK 61JBC 94JAM

- _____
- _____

Manufacturer: PHARMACIA

Shipping Instructions :

☒ TRANSMIT FOR RETURN AUTHORIAZTION AND RETURN TO CARDINAL HEALTH.

PARTIALS

YES ☐

NO ☒

A faxed response of your inventory status is REQUIRED

Please Fax: 1-888-724-1026 **Recall Number: 578RCL540**

ACCOUNT #_____ **Quantity on Hand** _____

ACCOUNT NAME_____

FOIA Confidential Treatment Requested By Cardinal

CAH 022382

CONFIDENTIAL

CAH_MDL_PRIORPROD_DEA07_01188688

P-14290 _ 00745

b.) Warehouse access shall be controlled by a Card Entry Access Control System or equivalent.

c.) Employees who require temporary access to the warehouse shall be issued "temporary passes" controlled by the Facility Manager or his designee.

4.) The facility must limit access to the controlled substance cage and the narcotic vault areas to only those employees who have a full-time cage or vault work assignment or their immediate supervisor.

a.) The Facility Manager shall maintain a list of employees authorized to have cage and/or vault access.

b.) Employees having job assignments that require short-term access to the cage and/or vault must be escorted by personnel with approved cage and/or vault access.

5.) Access to the computer room and computer system must be limited.

a.) Access to order entry, inventory adjustment and other screens that would allow for theft or diversion must be tightly controlled.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA18.00

TITLE: Business Continuity

ISSUE DATE: 6-5-2006

PAGE: 1 of 2

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA18.00**
TITLE: Business Continuity	**ISSUE DATE:** **PAGE:** 2 of 2

PURPOSE: To comply with FDA , State and Cardinal Health, Inc. requirements for emergency preparedness.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Pharmaceutical Distribution shall maintain and promulgate strict standards of loss control and develop a Business Continuity Plan which shall:

   a.) Prepare the Company and its distribution facilities to cope with immediate and long-range emergency situations;

   b.) Eliminate or minimize the causes of property loss; and

   c.) Enable the Company to distribute its products with maximum efficiency, free from either production or property loss.

2.) Each distribution facility shall train and educate appropriate employees in procedures outlined in the Business Continuity Plan. **(Refer to the Pharmaceutical Distribution Business Continuity Plan)**.

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA19.00

TITLE: Safe Medical Device Act

ISSUE DATE: 6-5-2006

PAGE: 1 of 4

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA19.00**
TITLE: Safe Medical Device Act	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To comply with the requirements of the Safe Medical Device Act (SMDA) and Cardinal Health, Inc. policy related to the recording and handling of medical device complaints.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) The facility must obtain the following for each medical device complaint received:

a.) Information from the reporting party:

i.) Name

ii.) Address

iii.) Telephone number

iv.) Type of facility (e.g. hospital, nursing home)

v.) Date of occurrence

vi.) Date of complaint

b.) Information regarding the device:

i.) Manufacturer's name

ii.) Brand or generic name

iii.) Model or catalogue number

iv.) Serial number or lot number

v.) Date of purchase

c.) Nature of the complaint if the complaint involves:

i.) Death

ii.) Serious injury

iii.) Serious illness

iv.) A malfunction which could result in death, serious injury, or serious illness if it recurs.

2.) Each complaint must be documented on a Medical Device Complaint Form **(Form FA19.00).**

3.) The facility shall provide all available information to the manufacturer of the device.

4.) The facility must retain on site all information concerning device complaints on file for the greater of:

a.) A period of two years from the date the complaint was received; or

b.) A period equivalent to the expected life of the device.

5.) The facility shall distribute and document the receipt of the SMDA Employee Guide **(Exhibit EA19.00)** to employees whose specific job function requires them to have this information.

FA19.00

SMDA REPORTING FORM

DATE: _____

REPORTING DISTRIBUTOR

Name: _____
Address: _____
_____
_____
Telephone Number: _____

SOURCE OF THE REPORT TO DISTRIBUTOR

Name: _____
Address: _____
_____
Telephone Number: _____
Type of Facility (e.g., hospital, nursing home) _____
Date of Occurrence: _____
Date of Report: _____

MANUFACTURER OF THE DEVICE

Name: _____

DEVICE INFORMATION

Brand or Generic Name: _____
Model or Catalogue Number: _____
Serial Number or Lot Number: _____
Purchase Date: _____

TYPE OF REPORTABLE EVENT

Death	☐
Serious Injury	☐
Serious Illness	☐
Malfunction	☐

REPORTING PARTY

Name: _____
Title: _____
Address: _____
_____
Telephone Number: _____

Signature: _____

FOIA Confidential Treatment Requested By Cardinal

CAH 022391

EA19.00

SAFE MEDICAL DEVICE ACT (SMDA)

General Requirements

Employee Guide

SAFE MEDICAL DEVICES ACT (SMDA)

GUIDELINES

The Safe Medical Devices Act of 1990 amends the Food, Drug and Cosmetic Act and contains provisions that affect distributors of medical devices. These provisions deal specifically with the recording of medical device incidents and complaints. A device distributor must establish and maintain device complaint records containing any incident information that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness or performance of a device.

Definitions

A *distributor* is defined as any person who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

A *malfunction* is defined as the failure of a device to meet any of its performance specifications or otherwise to perform as intended.

A *medical device* is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is:

1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,

2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals, or

3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for achievement of any of its principal intended purposes.

Recordkeeping Requirements

Device complaint files must be established and will include:

1. Any written or oral communication received concerning all complaints: and

2. A copy of all completed Medical Device Complaint Forms.

The files must be maintained by device and retained for two years from the date that the report or information is submitted to FDA or for a period of time equivalent to the design and expected life of the device.

What To Do When a Medical Device Complaint is Received

1. Obtain the following information from the reporting party:

   a) Name
   b) Address
   c) Telephone number
   d) Type of facility (e.g., hospital, nursing home)
   e) Date of occurrence
   f) Date of complaint

2. Obtain the following information about the device:

   a) Manufacturer's name
   b) Brand or generic name
   c) Model or catalogue number
   d) Serial number or lot number
   e) Date of purchase

3. Determine the nature of the complaint and if the complaint involves:

   a) Death
   b) Serious injury
   c) Serious illness
   d) A malfunction which could result in death, serious injury, or serious illness if it recurs.

4. Document the complaint on a Medical Device Complaint Form.

5. Provide information to the manufacturer of the device.

6. All information concerning the complaint is placed on file by device and maintained for two years from the date of the report or for a period equivalent to the expected life of the device.

RECEIPT OF SAFE MEDICAL DEVICE ACT EMPLOYEE GUIDE

I HEREBY ACKNOWLEDGE RECEIPT OF THE SMDA EMPLOYEE GUIDE.

I ALSO ACKNOWLEDGE THAT I HAVE READ THE SMDA GUIDE AND UNDERSTAND THE ACT'S REQUIREMENTS AS THEY APPLY TO MY SPECIFIC JOB FUNCTION.

EMPLOYEE SIGNATURE: _____

DATE: _____

WITNESS: _____

DATE: _____

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA20.00

TITLE: FDA Inspections

ISSUE DATE: 6-5-2006

PAGE: 1 of 5

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-5-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA20.00**
TITLE: FDA Inspections	**ISSUE DATE:** **PAGE:** 2 of 5

PURPOSE: To comply with Cardinal Health, Inc. requirements for handling regulatory inspections and provide guidance to division management.

SCOPE: Pharmaceutical Distribution facilities

POLICY:

1.) Upon notice of a FDA inspection, the facility must contact the Corporate Compliance Department immediately and provide the following information:

   a.) The nature of the visit.

   b.) The names of the inspectors.

   c.) The agency they represent.

2.) Upon arrival of the investigators at the facility, the manager, his/her designated alternate and/or the individual who has overall responsibility for FDA compliance shall meet with investigators and do the following:

   a.) Review their credentials (picture of person on an official ID card).

   b.) Accept the FDA Notice of Inspection.

3.) If there is any question as to the identity of the inspector, management shall not allow access to the facility until the following verification steps are taken:

   a.) Request the name and phone number of their immediate supervisor.

   b.) Contact the investigator's supervisor for verification.

   c.) If the facility cannot obtain verification, contact the Corporate Compliance Department for assistance.

4.) Inspectors shall be asked to sign the Visitor's Log and wear a Visitor Badge at all times while on the company premises.

5.) Management shall engage in a discussion with the inspector regarding the following:

a.) The purpose and extent of the investigation.

i.) Routine inspection

ii.) Recall effectiveness check

iii.) Sample collection

b.) Desire of management for a close-out discussion at the completion of the investigation.

6.) If FDA obtains samples, the facility shall:

a.) Request a receipt (FDA-484) from the FDA investigator for samples taken.

b.) Set up an account for the local FDA office and bill samples as a normal customer purchase.

c.) Obtain FDA's DEA registration number if samples are controlled substances.

7.) The facility shall give full cooperation to the inspecting authorities.

8.) Only persons authorized by management shall answer questions posed by investigators.

[redacted] **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA20.00**
TITLE: FDA Inspections	**ISSUE DATE:** **PAGE:** 4 of 5

9.) Inspections must be closely monitored by qualified personnel. The individual shall be prepared to:

a.) Immediately notify the personnel responsible for the various areas to be involved in the investigation prior to the investigators visiting the area.

b.) Explain the operation/type of security, record keeping and reporting systems/procedures maintained.

c.) Assist the investigators.

d.) Verify the accuracy of the information the investigators obtain from inventories, sales and purchases documents and make a list of records reviewed.

e.) Obtain copies for and retain copies of any documents the investigators requested.

f.) Assure that information volunteered is clearly beneficial to the facility.

g.) Assure no misrepresentations are given to the investigators.

h.) Note any suggestions or criticisms expressed by the investigators and immediately correct and document any violations discovered in this manner.

i.) Complete a daily detailed written record of the inspection which includes the following:

i. Any question raised by the inspector.

ii. Any question raised by the monitor.

iii. Any request made by the inspector.

iv. What the inspector was shown.

v. A list of any records viewed or copied by the inspector.

vi. Any suggestions of criticisms expressed by the inspector.

[redacted] CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL	POLICY NO: FDA20.00
TITLE: FDA Inspections	ISSUE DATE:
	PAGE: 5 of 5

10.) Once aware of any violations, the facility shall take the following initiatives in seeking and implementing corrective actions:

a.) Reconstruct the investigation and findings by using the same documents, facility review utilized by the investigator and the internal report prepared by the facility.

b.) Take appropriate action to correct any violations or problems uncovered during the investigation.

c.) Convey to FDA the corrective action taken, what steps the facility has taken to prevent future problems and inquire whether further action is necessary.

11.) All personnel shall be instructed not to read, acknowledge in any way, or sign any affidavit presented to any company employee by an inspector.

Reference: Exhibit EA20.00

Corporate Inspection Guidelines
Inspection Dos and Don'ts

- Receptionists must know whom to call when a regulatory agency inspector visits.
- Determine that an inspector is legitimate by examining his/her credentials.
- Require the inspector to sign in and wear a visitor's badge.
- Contact Corporate Compliance
- Receptionists or initial contact persons must inform all key employees that an inspector is present.
- Someone, but not a large number of individuals, must accompany the investigator and be with the investigator at all times.
- If the inspector is not familiar with the facility, describe the operations before entering the warehouse/production areas.
- At the beginning, review with the inspector all company policies and programs.
- Do not start an argument with, get intense with or lie to the inspector.
- Employees must be cooperative and seek to avoid conflict. Base discussions on the laws, regulations, guidances, etc.
- Understand the inspector's questions before answering. If needed, ask for an explanation. Refer each question to the most suitable employee.
- Answer only the question asked. Do not offer additional information unless it will benefit the company.
- Do not sign any affidavits without Legal department approval.
- Be sensitive to the compliance role of the inspector; do not threaten to call his/her supervisor when the inspector is doing his/her job.
- Deficiencies noted by the inspector must be corrected as soon as possible.
- Keep a detailed written record of the inspection.
- Keep duplicate copies of records/materials given to the inspector.
- During the exit interview, make sure that all deficiencies are adequately discussed. If there is disagreement, present all of the company information and any regulations and official interpretations that support the company's viewpoint.
- Submit a detailed written record of the inspection to Corporate Compliance.

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**FDA** **FDA21.00**
TITLE: Reporting Suspected Counterfeit Product	**ISSUE DATE:** 6-15-2006 **PAGE:** 1 of 3

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY** **REGULATORY COMPLIANCE MANUAL**	**FDA** **FDA21.00**
TITLE: Reporting Suspected Counterfeit Product	**ISSUE DATE:** 6/30/03 **PAGE:** 2 of 3

PURPOSE: To ensure that whenever a report of suspected counterfeit product is received specific information is obtained and documented appropriately and Cardinal Health Corporate Compliance is notified of the incident.

SCOPE: Cardinal Health Pharmaceutical Distribution facilities

PROCEDURE: Whenever a report of suspected counterfeit product is received from a customer the following steps shall be taken:

1.) The facility shall obtain the following information and complete a **Report of Suspected Counterfeit Product** form (Form **FA21.00**):

a.) Nature of complaint

b.) Customer name and account number

c.) Name of person making the call

d.) Invoice number on which the product was shipped

e.) Product Manufacturer

f.) Complete description of the product

g.) Product NDC Number

h.) Product Lot Number

i.) Expiration date

j.) Suspicious indications of potential counterfeit product, such as:

i.) Incomplete NDC Number

ii.) Change in package colors

iii.) Marks on the package

iv.) Missing information

v.) Incorrectly spelled information

vi.) Irregularities in the product container/closure system

2.) Facility will review current inventories of product and physically evaluate any current inventory of product with lot number indicated by customer.

a.) If the facility is able to confirm that product in inventory presents irregularities which suggest that the product may be counterfeit, that inventory will be immediately quarantined.

b.) Upon completing the inventory review, the facility shall immediately contact the Cardinal Health Corporate Compliance Department with the information supplied by the customer and the results of their inventory inspection, and await further instructions.

3.) Corporate Compliance will notify the appropriate state and federal agencies and the manufacturer of product within three (3) business days.

4.) All information concerning reports of suspected counterfeit product shall be placed on file and maintained for three years from the date of the report.

FA21.00

CardinalHealth

REPORT OF SUSPECTED COUNTERFEIT PRODUCT

Customer Information:

Nature of complaint: _____

Customer Name: _____

Account Number: _____ Invoice Number: _____

Caller's Name: _____

Product Information:

Product Manufacturer: _____

Product Description: _____

NDC / Number: _____ Lot Number: _____

Expiration Date: _____

Indication of suspected counterfeit product:

_____

_____

_____

Person completing form: _____ Date: _____

Cardinal Health Corporate
Compliance notified by: _____ Date: _____

CardinalHealth

CORPORATE QUALITY
REGULATORY COMPLIANCE MANUAL

POLICY NO:

FDA22.00

TITLE: Inventory Inspection and Quarantine of Suspected Counterfeit and Violative Product

ISSUE DATE: 6-15-2006

PAGE: 1 of 4

RESPONSIBILITIES:

APPROVALS:

Approved by: _____ Date: 6-15-06

Stephen J. Reardon
Vice President, Quality & Regulatory Affairs

CardinalHealth **CORPORATE QUALITY REGULATORY COMPLIANCE MANUAL**	**POLICY NO:** **FDA22.00**
TITLE: Inventory Inspection and Quarantine of Suspected Counterfeit and Violative Product	**ISSUE DATE:** **PAGE:** 2 of 4

PURPOSE: To identify the process for conducting an inventory inspection and, if needed, a quarantine of suspected counterfeit or violative product when requested by FDA or other regulatory agencies.

SCOPE: Cardinal Health Pharmaceutical Distribution facilities

POLICY:

1. Upon receiving a request from FDA or other regulatory agencies to check inventory for suspected counterfeit or violative product, the Vice President Quality & Regulatory Affairs shall immediately notify the following personnel:

   a.) Inventory Control Manager and the Director of Operations at each pharmaceutical distribution facility.

   b.) Vice President of Purchasing, Pharmaceutical Distribution

   c.) Senior Vice President Quality & Regulatory Affairs

NOTE: If the pharmaceutical distribution facility receives the original request, the facility must immediately contact the Vice President Quality & Regulatory Affairs.

2. The notification shall be sent via e-mail, using **Part A** of the **Inventory Inspection Request (Form FA22.00)**, and shall include, but not be limited to, the following information:

   a.) Item description

   b.) Lot number

   c.) Expiration date

   d.) Item number

   e.) NDC number

f.) Product manufacturer

g.) Reason for request

h.) Date of request

i.) Available descriptive information to aid in identification of suspected product

3. The Inventory Control Manager or his designee at the pharmaceutical distribution facility must inspect each piece of the noted product on hand.

   a.) Affected product must be placed in quarantine, in the Credit Return Department, and identified as such.

   b.) Affected product shall be held until the Vice President Quality & Regulatory Affairs issues instructions for disposition of the product.

4. The facility shall tag each affected product location with a **"PRODUCT ALERT"** tag **(Exhibit EA22.00)**. The tag shall remain in place for six (6) months from the posted date and must contain the following information:

   a.) Item number

   b.) Lot number

   c.) Expiration date

   d.) Additional information as recorded on the **Inventory Inspection Request** form.

5. The Inventory Control Manager or his designee at the pharmaceutical distribution facility shall notify the credit returns and receiving departments and provide them a copy of the completed **Inventory Inspection Request.**

6. Each facility must respond to the Vice President Quality & Regulatory Affairs with inventory findings within 24 hours of receipt of notification.

a.) Response shall be made via e-mail on **Part B** of the **Inventory Inspection Request**.

b.) Response shall be mandatory whether or not affected product is found.

c.) If additional affected product is received or a customer return is processed after the facility's initial response, the facility will report this information via e-mail to the Vice President Quality & Regulatory Affairs, using **Part C** of the **Inventory Inspection Request**.

7. Upon receipt of all facility responses, the Vice President Quality & Regulatory Affairs shall report the findings to:

   a.) FDA or appropriate regulatory agency.

   b.) Senior Vice President Quality & Regulatory Affairs

8. If a product recall is necessary, the facility shall refer to **SOP FDA17.00** for recall procedures.

9. The Vice President Quality & Regulatory Affairs shall serve as the primary contact person for FDA or the appropriate regulatory agency and provide information and/or documentation as required.

10. All information regarding inventory inspection and quarantine of suspected counterfeit or violative products shall be placed on file and maintained for three (3) years.

CardinalHealth

FA22.00

INVENTORY INSPECTION REQUEST

Please inspect your inventory for the following product. If suspected counterfeit or violative product is found, immediately quarantine product in the Credit Return Department.

PART A (to be completed by the Director of Quality Operations)

Product Information

Product Manufacturer: _____

Product Description: _____

Item Number: _____ NDC Number: _____

Lot Number: _____ Expiration Date: _____

Reason for Request: _____ Date of Request: _____

Additional Information: _____

PART B (to be completed by the distribution facility)

Inventory Findings

Pharmaceutical Distribution Facility: _____

Number of Suspected Counterfeit/Violative Inventory Units Found: _____

Additional information: _____

Person Completing Part B: _____ Date Completed: _____

PART C (to be completed by the distribution facility, if needed)

Additional Inventory Findings

_____

_____ b

_____

EA22.00

PRODUCT ALERT

ITEM #

LOT #

ADDITIONAL INFORMATION:

IF PRODUCT IS FOUND, NOTIFY SUPERVISOR IMMEDIATELY!

DATE POSTED:
(Tag must remain in place for 6 months from date posted)

CardinalHealth

Document Title	Issue Date	Document Number	
PROCESS TO ESTABLISH SOM THRESHOLD LIMITS	12/22/08	HSCSQRA-CAD-C002	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue New	Page [PAGE * MERGEFORMAT]	Change Number DCN-2278

1.0 PURPOSE

To outline the conceptual framework and methodology to follow when formulating threshold limits for the Suspicious Order Monitoring (SOM) program.

2.0 SCOPE

All HSCS Pharmaceutical Operations and Customers, Quality and Regulatory Affairs, Supply Chain Integrity

3.0 INCLUDED ATTACHMENTS AND FORMS

None

4.0 POLICY

The intent of calculating threshold limits is to establish a baseline purchase pattern for all monitored items. The baseline purchase pattern is then adjusted up by a statistically significant factor or variable to formulate the threshold limit. The subsequent implementation of threshold limits allows a SOM program to identify customers whose order pattern significantly deviates from the baseline or normalized purchase pattern.

Threshold limits are to be determined for all monitored items sold by, and all customers serviced by, each Business Unit. Monitored items include all controlled substances, List 1 chemicals, and state monitored items available for distribution within each Business Unit. A customer is defined as a unique DEA Registrant which has the ability to purchase a monitored item.

4.1 Definitions

DEA Registrant	A customer that is licensed by the DEA and that has the ability to purchase a monitored item.
Monitored Item	Includes any controlled substances, List 1 chemicals, or state monitored items. All monitored items are to be included within the SOM Program.
Segment	A classification system used to identify like DEA registrants. Segmenting customers allows for granularity when assessing purchase patterns and allows for the establishment of more precise threshold limits.
Drug Family	A series of associated controlled substances grouped together by the underlying chemical ingredient. Each monitored item is included within one drug family.
Base Code	The four digit value associated with each drug family.
Dosage Unit	A standardized measure of the quantity of doses per the sale unit of a controlled substance.
Threshold Limit	A value assigned by Quality & Regulatory Affairs that limits the quantity (dosage units) of monitored items within each drug family a customer may purchase.

4.2 Methodology

The following methodology outlines the steps to be followed when calculating threshold limits. Any variation or deviation from the below methodology must be approved by Corporate QRA.

CardinalHealth

Document Title	Issue Date	Document Number	
PROCESS TO ESTABLISH SOM THRESHOLD LIMITS	12/22/08	HSCSQRA-CAD-C002	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue New	Page [PAGE * MERGEFORMAT]*	Change Number DCN-2278

4.2.1 Extract and format list of customers and historical sales data.

a. Complete a unique customer roster containing each DEA Registrant that has purchased a monitored item, as well as a column indicating whether or not the customer is currently "active." "Active" is defined as having the ability to purchase a monitored item at the time of the data extract.

b. Compile all historical sales for all monitored items for all customers over the most recent 12 month time period. The 12 month time period should be based on the date the product was shipped.

c. Identify the number of monitored item drug families sold to the DEA Registrant. Threshold limits are to be calculated for each Base Code, or drug family, sold to each DEA Registrant.

4.2.2 Differentiate customers through segmentation. The segmentation of customers is preferred, but is an optional step.

a. Segmentation within the customers may occur by size or specialty, or a combination of both.

i. Any segmentation based on size must be based on the total quantity of monitored item dosage units purchased over a specified time period.

ii. Any segmentation done by specialty is to be based on DEA Activity Code. The DEA Activity Code is an alpha character assigned by the DEA to each DEA Registrant to identify the type of business category the Registrant is engaged in.

b. The segments must be tested prior to proceeding to the next step to ensure that an adequate sample size exists. The testing should encompass the following:

i. Review the total number of DEA Numbers within each segment to ensure that the segment contains at least 5% of all customers;

ii. Review the number of drug families purchased by customers within each segment to ensure that at least 50% of the drug families were purchased by at least 10% of the customers within the segment.

4.2.3 Evaluate historical controlled substance sales data per drug family, per month for each customer segment to establish appropriate threshold limits.

a. All historical invoice level purchases for all monitored items are to be aggregated by DEA Number, Base Code, and dosage units purchased per month.

b. Calculate threshold limits for each Base Code for all Customer

segments.

i. Threshold limits are to be calculated using consistent historical sales data. The intent is to remove erratic purchase patterns from the data as to not skew the threshold limit values.

ii. Determine the total dosage unit quantities purchased by segment per Base Code over the 12 month period.

iii. Identify the number of DEA Numbers who purchased each Base Code over the 12 month period for each segment.

iv. Determine the annual quantity per DEA Number for each Base Code for each segment.

v. Determine the monthly quantity per DEA Number per Base Code for each segment.

vi. Multiply the monthly quantity per DEA Number per Base Code for each segment by a factor of 3, 5, or 8. The multiplication factor of 3, 5, or 8 is to be implemented in the following manner:

- Three Factor : Hydrocodone, Oxycodone, Alprazolam, and Phentermine drug families;
- Five Factor : All remaining ARCOS reportable drug families;
- Eight Factor : All remaining monitored items not multiplied by a factor of three of five.

vii. To utilize a threshold calculated in this step, historical data from at least 3% of all customers included within the segment (with no less than 5 customers) must be utilized. For example, if the customer segment encompasses 100 customers, at least 3 customers must have consistent historical sales data in order to establish a threshold limit for the entire segment. This step ensures that a threshold limit for an entire segment is not based on the historical purchase pattern of one or two customers.

c. Conduct a gap threshold limit analysis. In the event that an adequate sample does not exist to formulate a threshold limit for a Base Code, initial threshold limits established for the segment by Deloitte will be used as a baseline. Any gap analysis is to be approved by the Manager and Vice President.

4.2.4 Incorporate KYC information to establish final threshold limits.

a. Adjustments can be made to the threshold limits based on background information, or “Know Your Customer” (KYC) documentation. The intent

CardinalHealth

Document Title	Issue Date	Document Number	
PROCESS TO ESTABLISH SOM THRESHOLD LIMITS	12/22/08	HSCSQRA-CAD-C002	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue New	Page [PAGE * MERGEFORMAT]/[PAGE *	Change Number DCN-2278

of this step is to adjust threshold limits based on the associated level of risk.

i. An example of this step would include increasing a customer's threshold limits by a % if the customer has a documented diversion or loss prevention program. In essence, Cardinal's role in the customer's anti-diversion decreases as the customer ability increases.

4.2.5 Apply rounding logic and finalize threshold limits.

a. Rounding logic is to be applied to finalize threshold limits. The rounding logic will vary by drug family and will be based on the standard package size sold.

i. An example of this step would be rounding a threshold limit (i.e. threshold value of 4,775) up to the nearest 500 because the standard package size is in increments of 500.

4.3 Conclusions All threshold limits are to be reviewed and approved by the Vice President of Anti-Diversion.

5.0 APPLICABLE DOCUMENTS None

Approvals on file in Healthcare Supply Chain Services (Transportation and Warehouse) Document Center			
Approvers:		Owner: Doc Center:	Jason Paul Snouffer
Change History			
DCN-2278	12/22/08	Initial release of new procedure, HSCSQRA-CAD-C002.	

CardinalHealth

Document Title	Issue Date	Document Number	
SALES – ANTI-DIVERSION ALERT SIGNALS	06/09/09	HSCSQRA-SAD-C003	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue 12/22/08	Page [PAGE * MERGEFORMAT]/[PAGE *	Change Number DCN-2423

1.0 PURPOSE

The Federal Controlled Substances Act requires pharmaceutical wholesalers to maintain effective controls to guard against the diversion of controlled substances. As part of this requirement, Cardinal Health has developed a Suspicious Order Monitoring (SOM) program to identify orders of unusual size, pattern, and/or frequency. This policy provides process requirements for the continuous monitoring and reporting of customer order activities by Sales during the execution of the SOM program. This process focuses on threshold event investigation activities.

2.0 SCOPE

This policy applies to Quality & Regulatory Affairs; Supply Chain Integrity; Cardinal Sales.

3.0 INCLUDED ATTACHMENTS AND FORMS

[HYPERLINK \l "ATTACHMENT1"]{- ~~HYPERLINK \l "ATTACHMENT1" }~~ Sales Highlight Report

4.0 POLICY

The Anti-Diversion team, within QRA, Supply Chain Integrity, is responsible for the continuous reporting of threshold events identified during the execution of the Suspicious Order Monitoring (SOM) program. The reporting encompasses two components: 1) Internal reports that assist in the evaluation of threshold events; and 2) Communication of the threshold events to the Sales department.

4.1 Definitions

Held Order	A held order occurs when a customer's accrual for a drug family in a given month surpasses the assigned QRA threshold limit. When this occurs, the order that exceeds the threshold limit is held pending Regulatory Review. Subsequent orders within the same drug family will be held as a continuation of the original event. These orders will not trigger a notification to sales but will appear as "held pending regulatory review" on customer invoice
Threshold Event	Is defined as the initial held order created by a DEA #, Base Code, Threshold Limit combination.
DEA Limit Over Threshold Report	A report generated by members of IT that contains all threshold events from a specified date.
Customer Profile	A report generated by QRA that contains various background, licensing, and analytical metrics relevant to the customer that assist in the evaluation of threshold events.
Distrack Held Order Report	A report generated by QRA that contains all current orders held as a result of the customer's accrual for a drug family exceeding the assigned QRA threshold limit.

4.2 Procedures for Reporting

The following procedures outline the process for the salesperson performing an inspection that looks for the Anti-Diversion alert signals.

CardinalHealth

Document Title	Issue Date	Document Number	
SALES – ANTI-DIVERSION ALERT SIGNALS	06/09/09	HSCSQRA-SAD-C003	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue 12/22/08	Page [PAGE * MERGEFORMAT]/[PAGE *	Change Number DCN-2423

4.2.1 Anti-Diversion alert signals

1. Salesperson searches for Anti-Diversion alert signals, including the following for most customers:
   - Pharmacies with minimal or no front end merchandise.
   - Pharmacies with little or no walk-in business.
   - Pharmacies with primarily cash customers.
   - Pharmacies ordering a high percentage of controlled substances relative to non-controlled substances.
   - Pharmacies ordering excessive quantities of a limited variety of controlled substances.
   - One or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled.
   - The pharmacy solicits buyers of controlled substances via the Internet
   - The following signs for Ambulatory Surgery Centers
     a. Is there only one individual responsible for ordering, monitoring and invoicing products? (these jobs should be handled by different individuals)
     b. Does the product that is received at the surgery centers match with the product that is entered into the system?
     c. Have any of the DEA registrants (pharmacies, physicians, dentists, nurse practitioners, etc) that are presently acquiring drugs ever had a DEA registration, state permit (pharmacy), or state controlled substance permit suspended, revoked or disciplined?
     d. High Average Daily Census (ADC) and/or average surgery case load/month (This is relative to their peer group)
   - The following signs for Physician's offices
     a. Is the physician's office excessively purchasing controlled substances? (This is relative to their peer group – if the physician's office is not dispensing to the public then it's control substance use should be minimal)
     b. Does the practitioner dispense directly to the public?
     c. Are the controlled substances stored in the cabinet or in any other secured place?
     d. Does the product received at the physician's office match the product entered into the system?
2. If the Customer exhibits 2 or more of the Anti-Diversion alert signals, then the salesperson is to complete the online survey at [HYPERLINK "http://www.cardinalhealth.com/customervisitsurvey" \o "http://www.cardinalhealth.com/customervisitsurvey"]{ ~~HYPERLINK "http://www.cardinalhealth.com/customervisitsurvey" \o "http://www.cardinalhealth.com/customervisitsurvey" }, and identify the risk level. This starts the QRA review process.

CardinalHealth

Document Title	Issue Date	Document Number	
SALES – ANTI-DIVERSION ALERT SIGNALS	06/09/09	HSCSQRA-SAD-C003	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue 12/22/08	Page [PAGE * MERGEFORMAT]/[PAGE *	Change Number DCN-2423

3. If no signs of diversion are noted, then the salesperson completes the inspection and the online form.

4.3 Responsibility — On an on-going, continuous basis, each individual Sales Representative is responsible for the execution of this SOP.

5.0 APPLICABLE DOCUMENTS

Customer Visit Survey	[HYPERLINK "http://www.cardinalhealth.com/customervisitsurvey" \o "http://www.cardinalhealth.com/customervisitsurvey"]{ ~~HYPERLINK "http://www.cardinalhealth.com/customervisitsurvey" \o "http://www.cardinalhealth.com/customervisitsurvey"~~ }

Approvals on file in Healthcare Supply Chain Services (Transportation and Warehouse) Document Center			
Approvers: Michael Mone'		Owner:	Nicholas Rausch
		Doc Center:	Jason Paul Snouffer
Change History			
DCN-2423	06/09/09	Complete re-write of entire procedure to conform to existing Cardinal Health practices.	
DCN-2287	12/22/08	Initial release of new procedure, HSCSQRA-SAD-C003.	

CardinalHealth

Document Title	Issue Date	Document Number	
SALES – ANTI-DIVERSION ALERT SIGNALS	06/09/09	HSCSQRA-SAD-C003	
Org. Office Healthcare Supply Chain Services Transportation and Warehouse Operations	Previous Issue 12/22/08	Page [PAGE * MERGEFORMAT]/[PAGE *	Change Number DCN-2423

ATTACHMENT 1

Suspicious Order Monitoring Update

For Sales Professionals

CARDINAL HEALTH CONFIDENTIAL – DO NOT DISTRIBUTE EXTERNALLY

To: Sales Professionals
From: Tom DeGemmis, SVP
Date: May 11, 2008
Re: Suspicious Order Monitoring Update

We have heard consistent feedback that more tools are needed to perform regular customer data checks. In response to this feedback, a new report has been created, which we have unofficially been calling *The Highlight Report*. The highlight report has been designed to give Sales a monthly snapshot of each customer's monthly total pharmaceutical sales, six month purchase history and the percentage of controlled sales to total Rx sales.

More specifically, this report has been designed to help you analyze changes in current month controlled substance orders against previous controlled substance orders. This data will help Sales to "Know Your Customer" and assist you with proactively taking a look at your accounts' ordering activities. This report will highlight which customers may be experiencing a change in business. There are three levels of increases that will require some action by the sales consultant, and these levels will all be highlighted by account and delivered to Sales in a monthly spreadsheet.

- **"Watch List" – 5 percent increase (at least $2,500) of controlled substance / List one chemical orders**
  Customers in this category should be added to the sales consultant's "watch list." No immediate action is required, but these accounts should be more carefully monitored. The PBC should discuss ordering trends with the account within 15 working days, either via phone or in person.

- **"Yellow Flag" – 10 percent increase (at least $5,000) of controlled substance / List one chemical orders**
  Customers in the "yellow flag" category will require more data. The PBC should contact the account quickly to discuss ordering trends (within 15 working days), but an immediate store visit is not required. The QRA Field Compliance Officer should be contacted as needed.

- **"Red Flag" – 15 percent increase (at least $10,000) of controlled substance / List one chemical orders**
  Customers in the "red flag" category should be visited ASAP by the PBC and/or QRA (within 10 working days). The PBC should contact Corporate QRA, as well as the local Field Compliance Officer, to work with this account to understand the reason for a drastic increase in controlled substance orders.

  **Any customer that falls into the watch list or yellow flag categories for three consecutive months must be escalated by the PBC to follow these red flag actions with the customer.*

The current month will be compared to a three-month rolling average of controlled substance sales. Please keep in mind that this is just a tool to help you analyze the controlled substance ordering activity of each of your accounts.

Conference calls will be set up in the first week of June to answer any questions you may have about this information. The first version of report, which will include April sales, will be sent via e-mail within the next few days. This report will not contain list one chemicals, which will be added in future reports. The first version of the report is in no way final as we plan to make adjustments as we go forward.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees by outlining the steps involved in the conduct of on-site investigations of CAH's customers to obtain information regarding their potential risk for diversion of regulated drugs.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and to meet or exceed DEA's expectations of distributors that have been communicated to CAH through informal, non-binding communications.

1.3 The purpose of this procedure is also to enable investigators to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site investigations after receiving permission from Director or Vice President of Supply Chain Integrity.

2.0 SCOPE

This procedure applies when CAH determines that an on-site investigation of a DEA-registered customer is necessary to meet the objectives outlined in Section 1.0 above. The procedures outlined apply to all retail pharmacies, including chain pharmacies. The procedure also applies to PARMED retail customers and dispensing physician customers for whom the Director of Supply Chain Integrity will maintain special case notes and report formats. This document also provides the investigators the ability to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site visits.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK \l "Attachment1"]{- ~~HYPERLINK \l "Attachment1"~~ }	Example Memo
[HYPERLINK \l "Attachment2"]{- ~~HYPERLINK \l "Attachment2"~~ }	Example Memo

[HYPERLINK \l "Attachment3"]{- HYPERLINK \l "Attachment3" }	Criteria for evaluating Large Volume Purchasers of Controlled and Monitored Substances
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }	Large Volume – Tactical and Analytical Committee Review Process

4.0 RESPONSIBILITIES

CAH Quality and Regulatory Affairs (QRA) investigators will be responsible for gathering information as set forth in this procedure using permissible methods like site visits, phone calls and email exchanges and will submit reports of investigation, case notes and supporting documentation to the Director of Supply Chain Integrity.

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC)	The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.
Case	An investigation of a customer conducted after a threshold event or after Cardinal Health learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
Case File	An individual file created within the case management system which is unique to a specific case and identified through the customer's DEA number. The file will serve as the investigative log in which all information collected regarding a specific case is to be documented.
Case Management	A manual or electronic system used by the Director to efficiently and effectively

ON-SITE INVESTIGATIONS

System	monitor and manage each case.
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
Customer	Any retail pharmacy customer regulated and properly licensed in good standing with the DEA and any other agencies as required by state or federal law for the purchase of regulated drugs.
DEA	Drug Enforcement Administration.
Director	Director, Supply Chain Integrity and Regulatory Operations or his designee. Note: the Director is a licensed pharmacist.
Distrack	Cardinal Health's warehouse management system that is utilized by Pharmaceutical Distribution Centers. This is an Automated Management System (AMS) and includes information such as customer names, inventory, orders, shipments, threshold, etc.
Investigator	An individual employed by Cardinal Health to conduct on-site investigations of customers at the direction of the Director. These individuals are stationed throughout the United States. At times, other QRA employees or QRA designees will also fill this role.
PBC	Cardinal Health sales personnel. Acronym for Pharmacy Business Consultant.
Regulated Drug	Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.
SOM	Suspicious Order Monitoring
Suspicious Order	A customer's order for a: • Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency; • List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or • Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event The initial held order for a regulated drug which exceeds the threshold set for a specified licensed customer. This is created by a DEA#, Base Code and Threshold Limit combination.

Vice-President Vice-President, Anti-Diversion & Supply Chain Integrity & Sr. Regulatory Counsel or his designee. Note: the Vice-President is a licensed pharmacist.

6.0 PROCEDURE

6.1 Receipt & Assignment of Cases

6.1.1 Receipt of Cases

6.1.1.1 Threshold events are recorded in the ADC system. A QRA pharmacist evaluates each threshold event according to established procedures and when appropriate, requests an investigation within ADC using any of the appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions).

6.1.1.2 The Director automatically receives an email notification generated by ADC and updates an Excel spreadsheet.

6.1.1.3 In addition, requests for on-site investigations of licensed customers due to reasons other than 6.1.1.1 (**e.g.,** requests from the Large Volume Purchaser Periodic Review Process or Controlled Substance Regular Purchaser Periodic Review Process) are made by the Vice-President and forwarded to the Director. The Director enters these requests into an Excel spreadsheet.

6.1.1.4 The Director must enter each case into a case management system or confirm that a case has already been entered.

6.1.1.5 The investigator, upon the Director or Vice President's permission, may choose an appropriate investigative method (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence other than site-visits.

6.1.2 Assignment of Cases

6.1.2.1 The Director must assign each case to an investigator.

6.1.2.2 Field investigators are located throughout the United States and are assigned to regions specified as North, South, East-Northeast, East-Southeast, and West. Each investigator will have the primary responsibility for all cases located within their region of responsibility. The Director will generally assign cases within a

region to the investigator assigned to that region. When needed to expedite a case or to increase efficiency and effectiveness the Director will make assignments to field investigators which may be outside their assigned region.

6.1.2.3 Upon making the assignment, the Director must document the assignment of the case in the case management system and notify the investigator.

6.1.2.4 On occasion, cases will be assigned to a QRA Compliance Officer based in one of CAH's distribution centers.

6.2 Investigative Process

6.2.1 General Principles

6.2.1.1 Investigators are responsible, with the assistance of the Director when necessary, for managing their own time to effectively and efficiently schedule, plan, execute, document, and report each assigned case within the established time frames.

6.2.1.2 Cases must be worked and the on-site visit to the licensed customer completed within a reasonable period of time (**e.g.,** 45 calendar days of assignment) when feasible. A final report must be completed and submitted to the Director or Vice President within a reasonable period of time (**e.g.,** 10 calendar days of the visit). Time extensions must be approved by the Director.

6.2.1.3 Priority cases may be assigned shorter time frames by the Director.

6.2.1.4 Investigators are expected to develop and share resources and individual expertise to achieve the objectives of the entire team.

6.2.1.5 Each investigation is divided into four basic parts: (1) initial case preparation; (2) background investigation; (3) site visit; and (4) preparation of reports.

6.2.1.6 Each of the four basic parts to the investigation must be documented by the investigator in the case file.

6.2.1.7 The Director must monitor the progress of cases and provide guidance and direction as necessary to develop and move the case to a successful conclusion.

6.2.2 Initial Case Preparation

6.2.2.1 Investigators are responsible for maintaining a current list of open cases assigned to them by the Director.

6.2.2.2 Following the general principles, investigators will select the cases for the next

round of facility visits. This decision process should include the age of the event, priority set by the Director, and proximity of pharmacies to one another.

6.2.2.3 Gather and review the information possessed by CAH regarding the case and the licensed customer. Depending on the case and customer, this may include, but is not limited to, information located in the following systems.

a. SOM / Anti-Diversion Centralization system information
b. Data from Tableau Reports generated from customer purchase history
c. Review activity of Controlled Substance (CS) drug identified in site visit request along with activity of all CS drug family to ascertain the need for closer look at those CS drugs
d. Content Manager (either through ADC or directly from Content Manager)
e. Distrack or any other relevant source

6.2.2.4 Develop a background research plan based upon the information obtained from CAH resources and personal investigative background and instincts. This background research should include the following.

a. Verification of customer licensing (DEA, Board of Pharmacy, etc.) information.
b. Review of threshold events and comments from the QRA Pharmacist requesting the site visit if appropriate and available.
c. Speaking with the QRA pharmacist requesting the site visit if deemed necessary.
d. Obtaining information about the customer from the PBC if appropriate.
e. Review of customer responses to questionnaires.
f. Review of previous decisions regarding shipment to the licensed customer.

6.2.2.5 Document relevant results of the initial case preparation rather than the process of case preparation within the appropriate case file. A sample of appropriate relevant results that can be included in the documentation of case preparation are:

a. Verification of the pharmacy's DEA registrant number and the classes of scheduled drugs the pharmacy is currently authorized to dispense.
b. State licensure verifications of both the pharmacy and the PIC/Owner.
c. Results of any other relevant internet research.
d. Tableau report analysis/summary providing the reader of the report a solid, factual, statistical analysis of the customer.
e. A statement concerning the ratio of controls to non-controls purchased.
f. The top 3 controlled drugs purchased and their strengths.
g. Total quantities and monthly averages for select drugs, usually the drug(s) of interest to the site visit.
h. A summary of the Tableau report analysis for the final ROI for readily

comparing and contrasting the Tableau data analysis to the pharmacy dispensing report analysis.

6.2.3 Background Investigation

6.2.3.1 Create a site visit schedule and make travel arrangements.

6.2.3.2 Follow through on the research plan to gather and review outside information and/or to verify information contained in CAH records.

6.2.3.3 Identify useful internet resources to conduct background and licensure information searches for the pharmacies and their employees. When appropriate, identify useful information on identified local physicians, identified local health care facilities, and obtain geographical or other relevant information.

6.2.3.4 Research, identify and/or verify:

a. Any disciplinary actions taken by licensing agencies taken against any of the licenses issued to the facility or to any of the owner/employees of the licensed customer; and
b. Any civil or criminal actions documented by federal/state/municipal courts or any other entity which permits access to public records that have been filed against any of the licensed customers, their employees, identified local physicians, or any other person associated with the facility.

6.2.3.5 Conduct an Internet search for any evidence that the facility has an Internet presence and to determine any adverse news story for the pharmacy, pharmacist, and known top prescribers of that pharmacy, if known.

6.2.3.6 Useful Internet resources will vary depending on the case itself as well the availability of the Internet site at any given time. Some potentially helpful Internet resources include the following:

a. Google
b. Reverse address and phone directory
c. Location photographs from Google Earth or Yahoo Maps
d. Wikipedia (city information)
e. Global Internet Management (DEA # verification)
f. Secretary of State (Corporate information)
g. Department of Health
h. State Board of Pharmacy
i. ZABA Search (personal information)

6.2.3.7 Personal contact with local, state, or federal agencies or law enforcement organizations may be necessary. Such contact must be approved by the Director.

6.2.3.8 Document this background investigation within the appropriate case file.

6.2.4 Investigator Contacts for On-Site Visits

6.2.4.1 When conducting a full site visit, approximately one week prior to an on-site visit, the investigator must communicate with an appropriate representative of the licensed customer to discuss the purpose of the visit and to set a date and approximate time for the visit. The contact person for a retail independent pharmacy is usually the pharmacist-in-charge or the owner of the pharmacy.

6.2.4.2 The PBC assigned to the licensed customer should also be contacted and provided the opportunity to be present during the visit. The PBC may also assist the investigator with setting up the visit (6.2.4.1).

6.2.4.3 In preparation for a full site visit, where possible and available, the investigator can choose to request from the pharmacist-in-charge (through the PBC or Sales Point of Contact where necessary) data that may include some or all of the following:

a. A list of the pharmacy's overall top 5 prescribers of controlled substances, with DEA numbers.
b. A list of the current pharmacists, with license numbers, who are regularly employed at this location.
c. A list of all nursing homes; assisted living facilities; group homes; hospices, that the pharmacy is currently servicing and an estimate as to the number of beds/patients being serviced at each location.
d. It is preferable if a computerized generated report can be provided to ascertain the following information, but if not, an estimate will suffice; over the past 30 days, overall, what percentage of customers pay cash for their prescription medications, this includes both controls and non-controls; of that overall percentage, what part of that percentage is for controlled substances (C-II thru C-V); finally, how is the controlled substance percentage then divided between C-IIs and all C-III-Vs combined (these two percentages should equal 100%); Cash paid = prescriptions filled that are NOT paid for in whole or in part by a third-party plan such as Medicaid, Medicare, private insurance, etc. Specifically, the patient pays for the full amount of the prescription on their own using cash, debit card, credit card or check.
e. A summary drug dispensing or usage report for all controlled substances (C-II thru C-V) dispensed over the past 3 months. This report should list total quantities dispensed by dosage units for each drug name and dosage. The report should not contain any patient specific information and, when feasible, not contain prescription specific dispensing information such as quantity per prescription.
f. If possible and available, a prescription count report that lists the top

prescribers of controlled substances (C-II thru C-V) by number of controlled substance prescriptions filled by the pharmacy for these prescribers over the past 30 days. The report should not contain any patient specific information.

g. If possible and available, the number (or range) of dosage units of controlled substances normally prescribed by each of the top 5 prescribers per prescription.

6.2.5 Site Visit

6.2.5.1 Data Collection Worksheets - Information collected during a site visit should be documented on a data collection worksheet which may be unique to the type of facility being visited and the level of visit being performed. Information collected on the data collection worksheet will serve as the basis for documentation of the visit in the case file.

6.2.5.1.1 The data collection worksheet is not all inclusive and should merely be used as a guide to collect uniform data applicable to the licensed customer. Investigators should be observant and are expected to include any additional information obtained which may assist in meeting the objectives identified in Section 1.0 of this procedure.

6.2.5.2 Potential Indicators of Diversion - Investigators should be particularly alert during the on-site visit to any potential Indicators of diversion. Indicators noted during the visit must be documented in the final data collection worksheet or memo and placed in the appropriate case file. Some indicators of potential diversion include the following:

a. Customers of the licensed customer exhibit drug seeking behaviors.
b. Customers coming to the pharmacy in groups to fill prescriptions (**e.g.,** groups of younger customers who appear to be familiar with one another, groups of people from outside the local area). Reports should be specific rather than general (**e.g.,** "4 males appearing to be in their twenties arrived in one vehicle and presented prescriptions to the pharmacy" rather than "a group of young males were observed filling prescriptions.").
c. Pharmacy customers who appear to be from outside the reasonable drawing area for the facility.
d. Evidence of illicit drug use around the facility (**e.g.,** used syringes, empty prescription containers).
e. Mailing materials or other evidence of operation of an Internet pharmacy.
f. High ratio of prescriptions for regulated drugs versus other drugs.
g. High ratio of regulated prescription drug stock to other prescription drug stock.
h. High ratio of particular strengths of drugs known to be widely abused.
i. Small or non-existent front end (non-prescription) drug stock.

j. Primarily cash transactions for regulated drug prescriptions.
k. One employee responsible for the ordering, monitoring, and invoicing of products.
l. High number of customers compared to their peers.
m. Lack of auditing processes around purchases.

6.2.5.3 **Area Scan** - Upon entering the community or immediate area of the licensed customer being visited, investigators should observe and document the surroundings and note any specifics which relate to the business practices, volume of business, and type of business of the licensed customer. These include, but are not limited to, the following:

a. Types and number of health care facilities located within the area.
b. Number and types of medical practices, especially noting those who have characteristically been heavy prescribers of controlled substances, such as, pain clinics, orthopedics, surgeons, oncologists, cancer centers, weight loss clinics, etc.
c. Unusually large numbers of individuals in the general vicinity of a physician's practice or of the facility.
d. General economic condition of the area in a factual manner (without speculation or subjective commentary.

6.2.6 **Setting the Tone for the Visit**

6.2.6.1 Investigators have no authority to require compliance with any request. Our ability to look at documents or to obtain information on-site is entirely dependent on the goodwill of the licensed customer. If the level of site visit requires contact with the pharmacy personnel, it is incumbent on the investigator to enter and approach appropriate personnel and immediately attempt to establish a good rapport with the customer. Our communicated intent should be to better understand the customer's business so that CAH can partner with the customer to identify and prevent diversion of controlled substances while providing superior service to our customers.

6.2.6.2 Be prepared to discuss how the Know-Your-Customer process works and attempt to answer simple and general questions regarding our process. However, do not discuss specific threshold levels. If unable to answer a question accurately, advise that you will obtain the information and get back to the customer. Contact the Director for guidance. For questions outside our area of responsibility and knowledge, attempt to have the customer pose the question to their PBC. If unable to do so, the investigator can forward the question to the PBC. If unsure how to proceed, contact the Director for guidance.

6.2.6.3 Remember, we are a guest of the licensed customer while in their facility and they may refuse to permit or provide one or more of your requests. The

investigator must not threaten or coerce the customer in an attempt to achieve compliance with the request. If there is a refusal which cannot be resolved and it is an important element of our fact gathering, the investigator should advise that the refusal may be considered in making decisions on the sale of controlled substances and other drugs of interest including other monitored drugs to the customer. If still refused, proceed with the visit to the extent permitted, but document the refusal in the case file.

6.2.7 Interview

6.2.7.1 If the level of site visit requires an interview of pharmacy personnel, the investigator should attempt to conversationally interview the appropriate personnel representing the licensed customer. The investigator should document the name and title of the person providing the information. The purpose of this interview should include the following:

a. Completing to the extent possible the data collection worksheet for the facility.
b. Obtaining additional information when responses reveal other areas of potential concern.
c. Attempting to resolve any issues which became evident during the initial preparation and background investigation including customer responses to questionnaires.
d. For facilities containing sterile areas, investigators must make the decision if they feel they need to go into the sterile area. Base the decision on criteria such as visibility into the sterile areas.

6.2.7.2 The investigator should be aware of any non-verbal cues or activity that indicates nervousness or potential deception (**e.g.,** failure to make eye contact, hesitation to provide routine information, nervous body movements, etc.).

6.2.7.3 If information is obtained during the site visit that is inconsistent with data obtained before, during or after the site visit, the investigator should note this in the final report.

6.2.8 Tour of the Facility

6.2.8.1 If the level of site visit requires a tour of the facility, the tour should include ALL areas of the facility. Ask for permission to take photographs of the facility. It is suggested that the investigator obtain photographs of:

a. the front of the prescription department;
b. the front end non-prescription drug section(s);
c. several prescription bays or shelves;
d. back room;
e. any automation; and

f. front of the facility from the outside

6.2.8.2 Use extreme care if photographs are taken of any indicators of diversion. DO NOT put yourself at risk. If the investigators believe that photographing indicators of diversion may jeopardize the investigator's safety, note with specificity the indicators of diversion, but do not photograph. Download all digital photographs to the case file.

6.2.9 Requesting Utilization Reports

6.2.9.1 If the level of site visit requires obtaining a drug utilization report, investigators should request one. Request that the report be prepared and sent electronically rather than hard copy or fax. Unless circumstances warrant otherwise, request drug utilization reports with the following characteristics:

a. Includes a summary of all controlled substances by drug and showing total quantity dispensed or administered during the time period.
b. Includes 3 months of usage data by month.
c. Data comes directly from the facility's computer system.
d. Does not include non-controlled drugs unless specifically requested.

6.2.9.2 Request that the submission include the complete facility name, address, phone number, DEA #, and contact person.

6.2.10 Investigative Analysis of Utilization Reports - How to Submit

6.2.10.1 The investigator will conduct an analysis of the summary dispensing report which includes the common drug families of concern. Usually this will include an analysis of the drug families Oxycodone, Hydrocodone and Alprazolam but may vary over time and region of the county. In addition, the investigator should add other drug families considered problematic for the particular case based on the preparation/background work, intelligence received, or direct observation.

6.2.10.2 The analysis will establish the average quantity dispensed per month for each of the drugs families analyzed.

6.2.10.3 Where appropriate, the investigator should also analyze specific dosage forms and strengths within certain drug families (**e.g.,** Oxycodone 30 mg products).

6.2.10.3.1 Individual results pertinent to the investigation will be documented in the final report.

6.2.10.3.2 The customer's summary dispensing report and the completed analysis will be placed in the case notes.

6.2.11 Final Report

6.2.11.1 Prior to preparing the final report, the investigator must research and confirm to the extent possible any additional information received during the on-site visit to the licensed customer.

6.2.11.2 The investigator must analyze the information collected and documented in the case file and formulate an assessment for presentation to the Director. The investigator's assessment must begin with the objective criteria set forth in [HYPERLINK \l "Attachment3"]{ ~~HYPERLINK \l "Attachment3" }~~. However, the investigator is free to use aggravating or mitigating considerations to provide an assessment derived from the objective criteria. Those aggravating or mitigating considerations must be appropriately articulated in the investigation report. The objective criteria are not the only factors that are to be considered as other facts and circumstances may indicate that diversion is likely or unlikely. The objective criteria are to be used as the starting point for the investigators assessment, but do not mandate the final assessment to be given. Investigators should consider all available facts and use their knowledge of pharmacies and diversion methods and trends and their professional judgment in making an assessment.

The options for the investigators assessment are:

a. Re-evaluate the customer after 12 or more months – if the facility does not currently present a significant risk for diversion; OR
b. Re-evaluate the customer after 3 months – if the facility does not currently present an immediate risk for diversion but may need to be re-evaluated after 3 or more months; OR
c. Re-evaluate the customer immediately – if the facility data or investigation warrants additional review by a senior member of the Anti-Diversion Supply Chain Integrity Leadership Team or the Large Volume Tactical and Analytical Committee.

6.2.11.3 The investigator must prepare a final report in the form of a memo (see [HYPERLINK \l "Attachment1"]{ ~~HYPERLINK \l "Attachment1" }~~ and [HYPERLINK \l "Attachment2"]{ ~~HYPERLINK \l "Attachment2" }~~.) For objective criteria table see [HYPERLINK \l "Attachment3"]{ ~~HYPERLINK \l "Attachment3" }~~

6.2.11.4 At a minimum, the memo must contain the name, DEA number, city, and state of the facility in the subject line. The body of the memo will contain:

a. An opening paragraph providing the date of the visit and the principle

individuals participating in the visit;
b. A summary of the findings in bullet point form, both positive and negative, considered in making the recommendation;
c. The assessment.

6.2.11.5 Findings bulleted in the final report should consist of a summary of the findings documented in the case file. Details should remain in the case file for review unless necessary to provide a proper perspective for the recommendation.

6.3 Analysis & Decisions

6.3.1 The Director must conduct a thorough, final review of each case and make a determination whether the case is complete and provides the information necessary to support an assessment of whether or not the customer needs to be re-evaluated by senior member(s) of the Anti-Diversion team immediately. The investigator will be contacted if necessary to clarify issues or to address questions regarding the case, the reports, and the assessment.

6.3.2 The Director must document within the case management system an approval of the assessment of the investigator. In the event that the Director comes to a different assessment, documentation must be made as an addendum to the final report with justification for the different assessment.

6.3.3 Once a final assessment has been made, a decision regarding whether to continue to supply regulated drugs to the customer must be made and appropriate follow-up steps initiated.

6.3.3.1 A decision to continue the sale of regulated drugs to the customer requires an evaluation of the customer's threshold limits for regulated drugs and adjustments when supported by findings documented in the case. The Director, or a QRA designee, must conduct such an evaluation and adjust thresholds appropriately.

6.3.3.2 A decision to discontinue the sale of regulated drugs to the customer requires the termination of the customer from the CAH system and notification to state and federal regulatory bodies.

6.3.4 If the customer was identified for site visit as a large volume purchaser as part of the Large Volume – Tactical and Analytical Committee Periodic Review Process (see SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }), the report will be submitted to that committee for final decision.

6.4 Types of Visits

6.4.1 The type of site visit to be conducted will be determined by the Director, the Vice President, or the committee requested the site visit.

6.4.2 Reconnaissance Visit - A reconnaissance visit is a site visit that does not require contact with pharmacy personnel or collection of documents or information from the pharmacy. This type of visit does not require advance coordination with the customer. The visit is intended to provide CAH with general information about the customer. This type of visit allows visibility of the customer's business without providing advance notice to the customer. In some cases, when significant information is already known about the customer and the customer's anti-diversion controls, this type of visit provides additional insight into the customer. Sections 6.2.6 through 6.2.9 do not apply to this type of visit. Portions of other sections of this SOP may not apply depending upon the availability of information collected prior to the reconnaissance visit.

6.4.3 Full Site Visit - A full site visit generally consists of all elements set forth in this SOP. However, the investigator may use sound judgment in determining the necessity and extent of specific investigative steps and inquiries.

6.4.4 Investigation other than by Site Visit – When appropriate, means of conducting a due-diligence other than by a site visit (**e.g.,** data requests, phone interviews, email interactions) may be chosen by the investigator only upon express written consent (**e.g.,** via email) from the Director. The Director must use his or her professional judgment to approve or disapprove the request and may choose to elevate the request to the Vice President of Supply Chain Integrity for a decision. Alternate means of investigation may also be used to augment a site visit.

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Investigators should avoid language that is speculative or subject to multiple interpretations in the reports and case notes.

7.1.2 The findings must be based on factual data, site visit observations and analysis of data gathered prior and during site visits.

7.1.3 Where appropriate and available, analysis of dispensing data, tableau data and other information must be documented in the case notes or threshold analysis files.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

Attachment 1

Cardinal Health
7000 Cardinal Place
Dublin OH 43017

CardinalHealth

Date	03/21/12	
To	File	
From	CAH Investigator	
Subject	Morse's Magnificent Pharmacy Austin, TX	AM0284XXX

This pharmacy was visited on March 10, 2012 by CAH Investigator YYY, SCI-QRA, CAH;
Met with John Doe, R.Ph, PIC/Owner. Site visit requested based on a customer due diligence exercise for select Medium and High Volume Customers OR held order review request from SCI Pharmacist Team; this customer is considered a medium volume customer for Oxycodone products; 161,500 Oxycodone units were purchased during a six month period, May through October 2011.

Findings

- Location/Area – Pharmacy is located on a well traveled street, in a suburban mixed business and residential area; it is located in the North Stafford Medical Park; there are several medical offices and an urgent care/primary care facility also located in the park
- Ratio of controls to non-controls dispensed is 25%
- Another wholesaler has recently refused to sell controlled substances to this pharmacy based on high volume of purchases
- The top prescriber of controlled substances, primarily oxycodone products, routinely prescribes quantities of controls in the 300-400 unit range per prescription
- Practitioners identified by the pharmacy as their primary prescribers of controlled substances all held active medical licenses and current DEA registrations
- No evidence of internet prescription sales or mail order service
- Percentage of cash sales involving controlled substances was reported as 4.4%
- Large number of walk-in customers were observed, and they appeared to be consistent with the local general demographics; nothing unusual was observed
- An average of 250 prescriptions are filled daily
- A summary drug utilization report was requested, received and analyzed; a copy was provided to QRA Anti-Diversion

Investigator Assessment

Based on the evaluation criteria provided, this pharmacy needs to be

ON-SITE INVESTIGATIONS

o Re-evaluate immediately
x Re-evaluate after 3 months
o Re-evaluate after 12 or more months

However, there are mitigating factors based on facts – (1.), (2.), (3.) – that may justify re-evaluating this pharmacy after 12 or more months

Attachment 2

Cardinal Health
7000 Cardinal Place
Dublin OH 43017

CardinalHealth

Date	03/15/12	
To	File	
From	Cardinal investigator	
Subject	Wonderful Care Pharmacy Lubbock, TX	AG376XXX

This pharmacy was visited on March 10, 2012 by Cardinal Investigator, Cardinal Health. Met with Tony Jones, Pharmacist-in-Charge. Report of controlled substance dispensing was not provided during visit and is pending at the time of this report. An addendum will be filed when the dispensing report is provided by the pharmacy.

Findings

- Location/Area –Located in a strip mall, surrounding by many stores on a busy four lane street, next to an intersection//Only 10% of the pharmacy business is from walk ins and prescribing physicians in the area//pharmacy delivers to a large number of assisted living facilities (ALF) in the San Diego area//bubble packs all medications at the pharmacy for delivery to these facilities//CAH distract lists this pharmacy as a managed care, closed door pharmacy but there is also some retail business
- Dispensing data was not requested
- Clonazepam continues to be a largely prescribed drug at the ALFs.
- No evidence of mail service or internet prescription sales//majority of business is delivered to ALFs
- The pharmacy had insignificant business dispensing OTC drugs
- Store was closed at the time of the visit, which was at 7:00 a.m.
- Mr. Owner declined permission for photographs to be taken of the store

Investigator Assessment
Based on the evaluation criteria provided, this pharmacy needs to be

x Re-evaluate immediately
o Re-evaluate after 3 months
o Re-evaluate after 12 or more months

ON-SITE INVESTIGATIONS

This is a unique situation which may warrant further evaluation. At this time the assessment is "Re-evaluate Immediately" based on the "*Criteria for Re-evaluate immediately - after 3 months - after 12 or more months Risk Assessment*" chart. Mitigating factors recommended for consideration in the final evaluation include:

1. The percentage of controlled substances filled as cash is affected by two factors: sale of compounded hormone products and providing service to uninsured clientele.
    i. Compounding of hormones include products containing testosterone. The pharmacy has a full compounding lab and markets their compounding services. Due to a lack of other compounding providers in Northwest Texas and Eastern New Mexico, the pharmacy services a large geographical area. Due to the volume of these medications shipped into New Mexico, the pharmacy is licensed in New Mexico as a non-resident pharmacy. It is common practice for compounders to charge cash for compounded medications due to lack of coverage or inability to adjudicate claims to third party payers.
    ii. Owner stated that the Lubbock area has a higher than average population without prescription insurance coverage. These customers will utilize other pharmacies for any medications on the $4 prescription list and trade with Caprock for all other medications. I witnessed an occurrence of this during my visit-an elderly man brought in a Schedule II prescription and I overheard his discussion with the technician that he could not afford the medication at Walgreens.
2. The Pharmacy Business Consultant did not make contact with this client with sufficient notice for him to print reports or familiarize himself with statistics for his facility. His answers were approximations. Full consideration should be reserved until information regarding his dispensing is obtained. I did request reports, but have not yet received the information.

Attachment 3

Objective Criteria	Re-evaluate immediately	Re-evaluate after 3 months	Re-evaluate after 12 or more months
Majority Source of Controlled Substance Patients	2 Prescribers	3-5 Prescribers	>5 prescribers
Total prescriptions filled per day	<100	100-200	>200
Patients per day per prescriber	>40	20-40	<20
Cash sales for all products	>30%	20-30%	<20%
Share of Controlled Substances Units*	>20%	15-20%	<15%
Number of Wholesalers (other than CAH) if more than 10% of controlled substances are purchased from other wholesalers	>3	2 or 3	1

*Based on estimated percentages of dispensed controlled substances from customer interviews and/or summary usage reports

This criteria table is used ONLY for Large Volume Purchasers identified by the Large Volume – Tactical and Analytical Committee for site visits (per SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }). The assessment is based on one or more criteria being met by the customer at the time of the visit. The investigator is free to use aggravating or mitigating considerations to provide an assessment other than the assessment set forth in the objective criteria. Those aggravating or mitigating considerations must be appropriately articulated in the investigation report. The objective criteria are not the only factors that are to be considered as other facts and circumstances may indicate that diversion is likely or unlikely. The objective criteria are to be used as the starting point for the investigators assessment, but do not mandate the final assessment to be given. Investigators should consider all available facts and use their knowledge of pharmacies and diversion methods and trends and their professional judgment in making an assessment.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE INVESTIGATIONS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Steve Morse PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
2962	12 Apr 2012	Scheduled Review	Yes	Corporate	COs & DOs Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the on-site investigation process.					
Change Description and Justification					
Scheduled review. Complete rewrite of entire procedure to conform with current Cardinal Health practices. Updated document to coincide with PDQRA formatting criterion.					

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees in the Quality and Regulatory Affairs (QRA) section on responding detecting and reporting suspicious orders, and processing, documenting and making judgments about threshold events, including making decisions about releasing or cutting orders that are suspicious or exceed a threshold.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, and extra-regulatory guidance to which DEA holds distributors responsible.

2.0 SCOPE

This procedure applies when an order is triggered by the CAH's Anti-Diversion Centralization (or equivalent) system for review by the QRA Pharmacist Group in order for the QRA Pharmacist to evaluate the order so as to meet the purpose of the procedure mentioned in 1.0 above.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C001.docx"~~ }	Daily Threshold Reporting
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/~~	SOM Threshold Limits

~~CAD-C002.docx" }~~

4.0 RESPONSIBILITIES

The responsibilities of the QRA Pharmacist team includes

a. Evaluating held orders
b. Identifying suspicious orders
c. Reporting suspicious orders to DEA
d. Performing a detailed review of suspicious orders and orders in excess of customer threshold for the drug family
e. Releasing suspicious orders and orders in excess of customer threshold for the drug family when appropriate
f. Cutting suspicious orders and orders in excess of customer threshold for the drug family when appropriate

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC — The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.

Anti-Diversion Customer Profile — A report generated by QRA containing various background, licensing, and analytical metrics relevant to a customer used to assist in the evaluation of threshold events.

DEA Limit Over Threshold Report — An IT generated report generated by members of IT that contains all threshold events from a specified date.

Threshold Event — The initial held order for a regulated drug which exceeds the threshold set for a specified customer. This is created by a DEA#, Base Code and Threshold Limit combination.

6.0 PROCEDURE

6.1 Initial Review

6.1.1 The following orders are held or cut pending review by QRA under this procedure

a. Orders of interest referred to by a distribution center
b. Orders that exceed a threshold set for the customer for the drug family

6.1.2 In addition, under this procedure, QRA can review other orders that may come to

QRA's attention based on any other criteria.

6.1.3 Under this procedure, QRA must first review EVERY held or cut order under 6.1.1 to determine whether the order is suspicious as that term is used in 21 C.F.R. 1301.74(b). Per the regulation, orders are deemed suspicious if they meet one or more of three criteria:

- **a.** Order is of unusual size
- **b.** Order is of unusual frequency
- **c.** Order deviates substantially from a normal pattern for the customer

6.1.4 Orders that meet one or more of the criteria in 6.1.3 must be reported to the DEA as suspicious.

6.1.5 **Orders of unusual size** are significantly larger than the orders normally placed by the customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.5.1 Orders of unusual size can be as a result of:

- **a.** Unintentional order entry errors (including duplicate order entries)
- **b.** Intentional orders placed by the customer

QRA personnel must use available information and prior experience to determine if the order is an unintentional order entry error or intentional order placed by the customer.

6.1.5.2 Unintentional order entry errors (including duplicate order entries) MUST NOT be reported as suspicious orders to DEA since the customer did not intend to place the order and MUST be cut with no changes to customer threshold and a readjustment of accrual to the level prior to the order entry error.

6.1.5.3 QRA personnel must use available information and prior experience to determine if the order of unusual size is intentional. If QRA personnel determines the order to be intentional and of unusual size then the order is deemed suspicious and MUST be reported to DEA.

6.1.6 **Orders of unusual frequency** are orders that occur significantly more frequently than the orders normally placed by the ordering customer or by customers that have a size and type of business that is similar to the ordering customer's business.

6.1.6.1 QRA personnel can use available information on order history and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order is of unusual frequency.

6.1.6.2 If the QRA personnel determines the order to be of unusual frequency then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.7 **Orders that deviate substantially from the normal ordering pattern** are orders that reflect a significant deviation from the customer's normal orders or that deviate substantially from the ordering patterns of customers that have a size and type of business that is similar to the ordering customer's business.

6.1.7.1 Substantial deviations in ordering patterns include, but are not limited to,

a. Orders for an unusually high percentage of controlled substances compared to non-controlled substances
b. Orders for an unusually high percentage of a particular strength of drug that is known or suspected of being widely diverted
c. Other deviations based on QRA personnel's experience

6.1.7.2 QRA personnel can use available information and prior experience on other customers that have a size and type similar to the ordering customer to determine if the order deviates substantially from the normal ordering pattern.

6.1.7.3 If the QRA personnel determines that the order deviates from normal ordering pattern then the order is deemed suspicious and MUST be reported to DEA by QRA.

6.1.8 At the end of 6.1, the customers held or cut order under 6.1.1 will be found in one of the following states.

6.1.8.1 Orders cut due to order entry errors and NOT reported to DEA.

6.1.8.2 Held or cut orders reported as suspicious to DEA.

6.1.8.3 Held or cut orders NOT reported as suspicious to DEA (**e.g.,** a non-suspicious order that exceeded a threshold).

6.1.9 ALL orders reported to DEA as suspicious should undergo Detailed Review Process set forth in 6.3.

6.2 Threshold Event Check on Orders

6.2.1 Any held or cut order under 6.1.1 (whether or not reported as suspicious to DEA) should be checked to see if the order is in excess of the threshold set for the customer for the drug family in the order.

6.2.2 If the order exceeds the threshold set for the customer, the order must be sent for Detailed Review Process set forth in 6.3 (Note that orders reported to DEA as

suspicious have already been assigned to the Detailed Review Process in 6.1.8).

6.2.3 If the order DOES NOT exceed the threshold set for the customer AND the order was not already reported as suspicious to the DEA, the order may be released to the customer using the process set forth in 6.4.

6.3 Detailed Review

6.3.1 Orders assigned for detailed review may arrive from any one of the following sources

a. Orders reported as suspicious to DEA not exceeding thresholds set for the customer
b. Orders exceeding thresholds set for the customer but not reported to the DEA as suspicious
c. Orders reported as suspicious to DEA AND exceeding thresholds set for the customer

6.3.2 The level of review will be determined by the unique facts and circumstances of each matter, including the customer's historical ordering pattern, information in the QRA file about the customer, the context of the order and the facts that are obtained in the early stages of review.

6.3.3 Document the relevant information considered and decision point factors used in the detailed review.

6.3.4 If after completing the steps in detailed review process (6.3) the QRA personnel do not have sufficient evidence to determine that the order is not likely to be diverted into other than legitimate channels the order must be cut using process in 6.5.

6.3.5 If the QRA personnel is unable to conduct the necessary level of detailed review (6.3) due to any reason (including but not limited to non-cooperation from the customer)

a. The order must be cut (6.5).
b. The customer must be referred to the Vice President, Supply Chain Integrity, to determine appropriate course of future action.

6.3.6 If after completing the steps of the detailed review process (6.3) the QRA personnel determines that the order is not likely to be diverted into other than legitimate channels the order may be released using release process (6.4).

6.4 Orders Subject to Release

6.4.1 After initial review process (6.1), if the QRA personnel determines that the order is not suspicious AND the order does not exceed the threshold set for the customer the order can be released.

6.4.2 After the detailed review process (6.2), if the QRA personnel determines that the order is not likely to be diverted the order can be released.

6.4.3 Before the order can be released, QRA personnel must ensure that the reasons for releasing the order and relevant information considered (see 6.3.3) have been recorded.

6.4.4 Determine if the customer's threshold levels should be considered for adjustment following the SOM Threshold Limits ([HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx"]{~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C002.docx" }) standard operating procedure.

6.5 Suspicious Orders Not Subject to Release

6.5.1 Cut orders in ADC and leave accrual limiter unchanged.

6.5.2 If the order has already been reported to DEA as suspicious, no additional action is required.

6.5.3 If the order has not been reported to DEA as suspicious (as in the case of orders not deemed suspicious during initial review 6.1, but deemed suspicious after detailed review 6.3), report the order to DEA when the order is cut.

6.5.4 The customer whose order has been cut and reported to DEA as suspicious must be referred to the Vice President, Supply Chain Integrity to determine appropriate course of future action, if in the professional judgment of the QRA personnel, the suspicious order raises concerns about the customer's ordering, distributing and/or dispensing of controlled substances.

6.5.5 Report suspicious order to other regulatory bodies as required.

7.0 DOCUMENTATION REQUIREMENTS

None

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

DETECTING AND REPORTING SUSPICIOUS ORDERS AND RESPONDING TO THRESHOLD EVENTS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Christopher Forst PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
2962	12 Apr 2012	Scheduled Review	Yes	Corporate	Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the detecting and reporting suspicious orders and responding to threshold events procedure.					
Change Description and Justification					
Scheduled review. Complete Rewrite of entire document to properly define the process for detecting and reporting suspicious order and responding to threshold events. Updated document to coincide with PDQRA formatting criterion.					

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE QRA AND SURVEILLANCE INVESTIGATIONS

1.0 PURPOSE

1.1 The purpose of this procedure is to provide guidance to Cardinal Health (CAH) employees by outlining the steps involved in the conduct of on-site investigations of CAH's customers to obtain information regarding their potential risk for diversion of regulated drugs.

1.2 The purpose of this procedure is also to comply with or exceed the standards for distributors set forth in the Controlled Substances Act, regulations promulgated pursuant to that Act, to meet the obligations set forth in the Administrative Memorandum of Agreement (MOA) effective May 14, 2012, and to meet or exceed DEA's expectations of distributors that have been communicated to CAH through informal, non-binding communications.

1.3 The purpose of this procedure is also to enable investigators to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site investigations after receiving permission from the Director or Vice President of Supply Chain Integrity.

2.0 SCOPE

This procedure applies when CAH Quality and Regulatory Affairs (QRA) determines that an on-site investigation of a DEA-registered customer is necessary to meet the objectives outlined in Section 1.0 above. The procedures outlined apply to all retail pharmacies, including chain pharmacies. The procedure also applies to KINRAY and PARMED retail customers and dispensing physician customers. This document also provides the investigators the ability to choose appropriate permissible investigative methods (**e.g.,** data requests, phone interviews, email interactions) to perform due diligence in addition to or in lieu of on-site visits.

3.0 REFERENCES / RELATED DOCUMENTS

[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"]{- ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/~~		Detecting and Reporting Suspicious Orders and Responding To Threshold Events

CAD-C007.docx" }	
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form1.xlsx" }	QRA Site Visit Form
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form2.xlsx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C008-Form2.xlsx" }	Surveillance Site Visit Form
[HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{- HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }	Large Volume – Tactical and Analytical Committee Review Process

4.0 RESPONSIBILITIES

The designated CAH employee(s) responsible for Suspicious Order Monitoring (SOM) have the primary responsibility for compliance to this procedure.

5.0 DEFINITIONS

Anti-Diversion Centralization (ADC)	The Anti-Diversion Centralization application brings together information for case analysis that currently resides in several computer applications and allows QRA personnel to examine case information in one convenient location and handles actions performed by QRA personnel like cutting, releasing and reporting suspicious orders.
Case	An investigation of a customer conducted after a threshold event or after Cardinal Health learns other information that warrants an on-site investigation to obtain the information necessary to assess the customer's potential risk for diversion.
Case File	An individual file created within the case management system which is unique to a specific case and identified through the customer's DEA number. The file will serve as the investigative log in which all information collected regarding a specific case is to be documented.
Case Management System	A manual or electronic system used by the Director to efficiently and effectively monitor and manage each case.
CFR	Code of Federal Regulations
CSA	Controlled Substances Act
Customer	Any retail pharmacy customer regulated and properly licensed in good standing with the DEA and any other agencies as required by state or federal law for the purchase of regulated drugs.
Customer Category	The category to which the customer belongs based on three month average monthly volume for the drug family leading to the customer site visit request as set by the Vice-President
DEA	Drug Enforcement Administration.
Director	Director, Supply Chain Integrity and Regulatory Operations or his designee. Note: the Director is a licensed pharmacist.
Distrack	Cardinal Health warehouse management system that is utilized by Pharmaceutical Distribution Centers. This is an automated management system and includes information such as customer names, inventory, orders, shipments, threshold, etc.
Investigator	An individual authorized by Cardinal Health to conduct on-site investigations of customers at the direction of the Director. These individuals include QRA employees, designated Cardinal Health employees, or authorized outside

contractors.

PBC Cardinal Health sales personnel. Acronym for Pharmacy Business Consultant.

Regulated Drug Controlled substances, List 1 and 2 Chemicals, and other drugs required to be monitored by individual states.

SOM Suspicious Order Monitoring

Suspicious Order A customer's order for a:

- Controlled substance which is of an unusual size, deviates substantially from a normal pattern, or is ordered with unusual frequency;
- List 1 or 2 Chemical which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the listed chemical will be used in violation of the federal Controlled Substances Act; or
- Drug required to be monitored by an individual state which is of an extraordinary quantity, involves an uncommon method of payment or delivery, or any other circumstance which may indicate that the drug may be used in violation of state law.

Threshold The maximum quantity of a regulated drug permitted to be automatically shipped to a specific licensed customer.

Threshold Event The initial held order for a regulated drug which exceeds the threshold set for a specified licensed customer. This is created by a DEA#, Base Code and Threshold Limit combination. These thresholds are designed as trigger points to review and evaluate an order. Orders that reach the threshold are not necessarily suspicious. An evaluation is required once an order reach the thresholds to determine if they are suspicions.

Vice-President Vice-President, Anti-Diversion & Supply Chain Integrity & Sr. Regulatory Counsel or his designee. Note: the Vice-President is a licensed pharmacist.

6.0 PROCEDURE

6.1 Receipt and Assignment of Cases

6.1.1 Receipt of Cases

6.1.1.1 Site visit cases are received from two sources:

a. QRA Pharmacists request a site-visit to a pharmacy based on the totality of circumstances for suspicious orders (or order lines) following SOP [

HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C007.docx" }.

b. The Large Volume Tactical and Analytical Committee selects certain customers considered to present a higher risk of diversion based on criteria like volume of controlled substance purchases, growth in controlled substance purchases and others factors following SOP [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }.

6.1.2 Assignment of Cases

6.1.2.1 The Director assigns cases in customer categories as determined by current procedure to QRA site visit investigators and/or external contractors.

6.1.2.2 QRA investigators or contractors must complete the site visits within a reasonable period of time (**e.g.**, within 30 calendar days) and submit the report within a reasonable period of time after the visit (**e.g.**, 10 calendar days)

6.1.2.3 The Director assigns cases in customer categories as determined by current policy to Sales Team or other CAH employees for surveillance site visit and QRA Analytics team for pharmacy data collection.

6.1.2.4 Sales team or other CAH employees must complete the surveillance site visits within a reasonable period of time (**e.g.**, within 7 calendar days) and submit the report to QRA analytics within a reasonable period of time after the surveillance visit (**e.g.**,10 calendar days)

6.1.2.5 For surveillance visits, QRA Analytics team must complete data gathering and analysis within a reasonable period of time (**e.g.**, 7 calendar days) and submit the completed surveillance report to Director or Vice-President for review

6.1.2.6 After review and approval by the Director or Vice-President, the file will be uploaded on the QRA content manager and available for review by the QRA pharmacist

6.2 QRA Investigator (or Contractor), or other CAH employees Site Visit Process

6.2.1 Background Preparation

6.2.1.1 Contact relevant PBC or Sales Manager to inform of the site visit and arrange for the site visit

6.2.1.2 In preparation for the site visit, where possible and available, the investigator can choose to request from the pharmacist-in-charge, pharmacy owner or their representative (through the PBC or Sales Point of Contact, or other CAH employees where necessary) data that would assist in the evaluation of the pharmacy. The preparation of the report can be initiated with the information obtained via phone, fax of email.

6.2.1.3 Gather and review the information possessed by CAH regarding the case and the licensed customer. Depending on the case and customer, this may include, but is not limited to, information located in the following systems:

a. SOM / Anti-Diversion Centralization system information
b. Data from Tableau Reports generated from customer purchase history
c. Review activity of Controlled Substance (CS) drug identified in site visit request along with activity of all CS drug family to ascertain the need for closer look at those CS drugs
d. Content Manager (either through ADC or directly from Content Manager)
e. Distrack or any other relevant source

6.2.1.4 Perform internet search - **e.g.**, some helpful Internet resources include the following:

a. Google
b. Reverse address and phone directory
c. Location photographs from Google Earth or Yahoo Maps
d. Global Internet Management (DEA # verification)
e. Secretary of State (Corporate information)
f. Department of Health
g. State Board of Pharmacy
h. ZABA Search (personal information)

6.2.1.5 Scan any items of concern (**e.g.**, disciplinary actions against the pharmacy or its top prescribing physicians, records of DEA license suspension, and current investigations).

6.2.1.6 Record relevant information from background search on the site visit form and answer if the background research was acceptable on the pharmacy. Explain if background research was not acceptable.

6.2.2 Site Visit

6.2.2.1 Information collected and observed during the site visit should be reported and recorded on the site visit report template provided by the director.

6.2.2.2 Follow the site visit report template and ask questions in dispensing information, dispensing analysis, know-your-customer, due-diligence sections.

6.2.2.3 For each section populate the answers as available in the site visit report and follow the worksheet.

6.2.2.4 Seek and record explanations to questions that would help assess if the controlled substances prescriptions are being filled for legitimate medical purpose.

6.2.3 Completing Site Visit Report Sections

6.2.3.1 Dispensing information section contains questions on;

a. Average number of total prescriptions per day
b. Average number of total prescriptions paid in cash per day
c. Average number of controlled substance prescriptions per day
d. Average number of controlled substance prescriptions paid in cash per day
e. Higher level of dispensing of most likely to be diverted strengths of Oxycodone, Hydrocodone, Alprazolam and all other controlled substances of interest

The actual numbers may be obtained from the customer. If the actuals are unavailable, the investigator should request the pharmacist to provide an estimate.

- Explanations should be sought if the percentage of controlled substance prescriptions paid for in cash is significantly higher than benchmarks.
- Explanations should also be sought if the percentage of controlled substance prescriptions paid in cash is significantly higher (**e.g.**, larger than 4%) than that of the non-controlled substances paid for in cash.
- Explanations should also be sought if a high level dispensing of most likely diverted strengths is observed including details of prescribers contributing to the higher level dispensing of most likely diverted strengths of controlled substances.

6.2.3.2 Dispensing analysis section of the report requests average monthly dosage units (over the previous 3 to 6 months depending on data availability) dispensed for 13 most likely to be diverted drug families. If this data is not readily available, use CAH sales data to complete this section to get an idea of the monthly usage rate

of the pharmacy. Complete this section only for those controlled substance drug products that are of interest to CAH at this pharmacy – drugs of interest include drug families (among the 13 most likely diverted drug families) that were flagged as part of the suspicious order reporting process, Large Volume Tactical & Analytical Committee review process or any from any other QRA processes or sources.

Analyze dispensing data for the following substances:

a. Oxycodone
b. Hydrocodone
c. Alprazolam
d. Hydromorphone
e. Oxymorphone
f. Carisoprodol
g. Methadone
h. Fentanyl
i. Morphine Sulfate
j. Zolpidem
k. Clonazepam
l. Methylphenidate
m. Amphetamine salts

6.2.3.3 Based on CAH sales data in Tableau or other tools, investigate if any of the drug families of interest experience disproportionate growth in the past 12 months and investigate the reasons why.

6.2.3.4 Know-your-customer section addresses such questions as:

a. Who are the main healthcare providers in the pharmacy's draw area?
b. What are the estimates of total, Controlled Substance (Schedule 2) and Controlled Substance (Schedules 3-5) purchased across all wholesalers at the pharmacy customer?

6.2.3.5 Due diligence section of contains questions on:

a. Whether the pharmacist employs his or her corresponding responsibility;
b. Explanation of the due-diligence steps taken by the pharmacist to ensure that controlled substance prescriptions are being filled for legitimate purposes;
c. Questions on possible diversion indications such as:
   - There were long queues outside the pharmacy
   - The patients and customers at the pharmacy were NOT congruent with the demographics and economics of the area?
   - Disproportional Out-of-state vehicles were parked outside the

pharmacy
- Any evidence of illicit drug use around the pharmacy (used syringes, empty prescription containers etc.)
- Presence of any mailing materials or any other evidence of an internet pharmacy?
- Any other obvious signs of diversion at the pharmacy during the site visit?

6.2.4 Site Visit Assessment

6.2.4.1 Based on the totality of observations and analysis made by the investigator, determine whether the pharmacy needs an immediate re-evaluation by the originator of the site visit request (Director, Vice-President or Large Volume – Tactical and Analytical Committee).

6.2.4.2 Provide any additional explanation or observations that the corporate reviewer (Director, Vice-President or Large Volume – Tactical and Analytical Committee) may need to consider in their evaluation.

6.2.4.3 The Corporate Reviewer (Director, Vice-President or Large Volume Tactical and Analytical Committee Representative) will complete the Reviewer Assessment and Decision section, record the decision and reasons behind the decision according to procedures specified in [HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx"]{ ~~HYPERLINK "http://collab.cardinalhealth.net/sites/pdqra/Controlled%20Document%20Library/CAD-C023.docx" }.

6.3 Sales, QRA Investigator, other CAH employees or Contract Surveillance Site Visit Process

6.3.1 Background Preparation

6.3.1.1 The QRA analytics team will begin data collection directly from the pharmacy for retail independent pharmacies and from corporate offices for chain pharmacies.

6.3.1.2 Surveillance investigator will visit the customer unannounced

6.3.2 Site Visit Report Completion

6.3.2.1 The surveillance investigator must complete basic customer information, due diligence and investigator assessment sections in the surveillance site visit report template.

6.3.2.2 The QRA analytics team will complete the remaining sections of the surveillance site visit report wherever data can be obtained from the customer:

7.0 DOCUMENTATION REQUIREMENTS

7.1 Documentation Guide(s) and Practices

7.1.1 Investigators should avoid language that is speculative or subject to multiple interpretations in the reports and case notes.

7.1.2 The findings must be based on factual data, site visit observations and analysis of data gathered prior and during site visits.

7.1.3 Where appropriate and available, analysis of dispensing data, tableau data and other information must be documented in the case notes or threshold analysis files.

7.2 Documentation Retention

7.2.1 All documents must be loaded onto CAH QRA Content Manager within a reasonable period of time.

CardinalHealth

Standard Operating Procedure
Pharmaceutical Distribution

ON-SITE QRA AND SURVEILLANCE INVESTIGATIONS

Approvals					
Approvals on file in the Pharmaceutical Distribution Corporate Document Center Approvers: Michael Moné				Owner: Steve Morse PDCDC Coordinator: Jason Paul Snouffer	
Change History					
DCN	Effective Date	Change Type	Training Required	Document Applicability	Training Assignment(s)
3006	06 Jun 2012	Modify	Yes	Corporate	COs & DOs Other
Other (specify)					
Training assignments to Corporate Anti-Diversion personnel who are involved in the on-site investigation process.					
Change Description and Justification					
Document was revised to reflect the updated on-site QRA and surveillance investigations, two new forms were created to aid in the investigators.					

Scope

This policy is limited to Retail Independent and Retail Chain customers ordering controlled substances through the core pharmaceutical distribution business[1], as well as the thirteen drug families[2] designated as having a high risk for abuse and diversion. The policy applies to all individuals who have the ability and/or direct responsibility for assessing and adjusting customer threshold limits for the aforementioned customers and drug families.

Effective Date

January 15, 2013

Policy Statement

Cardinal Health's QRA department will have a standardized method to assess and adjust threshold limits utilized within the electronic monitoring system of the Suspicious Order Monitoring (SOM) program.

For purposes of this policy, the assessment and adjustment process is outlined from initiation to conclusion. The initiation of an assessment could result from an early dialogue notice, held order, or proactive communication from the customer or sales department. The assessment could conclude with no change of a threshold limit, an increase or decrease of a threshold limit, resolution of a held order, and/or the report of a suspicious order to DEA.

The following outlines the sequence of steps and corresponding decisions that should generally occur for each type of assessment.

1. **Determine customer's class of trade:** The policy only applies to Retail Independent and Retail Chain customers. If the customer's class of trade is Retail Independent or Retail Chain, proceed to step 2.

    a. Class of trade can be found within ADC, indicated as Business Activity, on the Account Info tab of the Customer Details dashboard.
    b. Customers within other classes of trade are to be managed by the Director of Pharmacy or designated individual on that team.

2. **Evaluate type of assessment:** Three distinct mechanisms may initiate the need to review a customer's threshold limit. These mechanisms include:

    a. Held order: order held by the electronic monitoring system, occurring when a customer's accrual exceeds the threshold limit. All orders held by the electronic monitoring program will appear in ADC.
    b. Early dialogue: notification that occurs when a customer's accrual approaches the threshold limit. All early dialogue notifications will appear in ADC (and a case may be created if step 3 concludes that an assessment is warranted).
    c. Proactive review: occurring when a sales representative or other party proactively communicates to QRA the potential need for review. The communication could occur via email or via a phone conversation.

[1] Core pharmaceutical distribution business includes customers serviced by the 20 forward distribution centers.
[2] See Appendix 1 for the List of 13 Drug Families.

3. **Determine if assessment is warranted:** An evaluation of the set of circumstances specific to each customer is needed in order to determine if an assessment of the threshold limit is warranted. The set of circumstances reviewed should generally include the following for each type of assessment.

   a. Held Orders: orders held by the electronic monitoring program will appear in ADC and require action, but not necessarily an assessment of the threshold limit. The following steps should generally occur to evaluate the held order and assist in determining if an assessment is warranted.

      a. Evaluate case within ADC, which appears on the dashboard.
      b. Identify customer by specifically reviewing the DEA #, name, location and class of trade.
      c. Determine the drug family for which the evaluation is generated by. This will be noted within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard. Assess recent cases regarding the same drug family, or other drug families, to understand previous decisions and actions completed. This information can be found within ADC, indicated as Substance, on the Customer Cases tab of the Customer Details dashboard, as well. Opening a previous case and reviewing the Order Processing portion of the screen will outline the actions taken for that previously held order.
      d. If the customer's class of trade is Retail Chain, determine Cardinal Health's distribution position.[3] Analysis will vary depending on whether Cardinal Health is the customer's primary wholesaler or in some other distribution position.
      e. Review customer comments found within ADC on the QRA Info tab of the Customer Details dashboard. Use these comments to determine if any new information has been included since the prior review and, if so, determine the value of this new information in your analysis of the customer.
      f. Review any new or pertinent due diligence documents which are found within ADC on the Customer Profile Tab of the Customer Details dashboard. Any documents that have been added within the last year may be valuable to the analysis.
      g. Review the specifics of the held order to determine order size, accrual, and threshold. Accrual within ADC, indicated under Volume, on the Customer Cases tab of the Customer Details dashboard.
      h. Define Customer Zone within Tableau file, to determine the necessary requirements for customer analysis and threshold adjustments which can be found in Table 2: Customer Segmentation and Review Policies.[4]

   b. Early Dialogue:

      a. Review Early Dialogue within ADC to determine instances where communication may be necessary. Those Early Dialogue cases that are 85%-99% of accrual should be reviewed daily. To view cases within ADC, select Early Dialogue at the top of the Anti-Diversion Centralization – QRA Dashboard and filter to designated region by selected Region at the bottom of the screen.

[3] See Appendix 6 for Cardinal Health Distribution Position.
[4] See Appendix 2 for Customer Segmentation and Review Policies.

b. Evaluate the instance within ADC to determine:
c. If the customer had been assessed within the last two (2) weeks (what do you think of this timeline? Please change to something more appropriate, if you think 2 weeks is too long/short.) regarding the specific drug family.
d. If new due diligence documents have been received or collected since the previous assessment. Be sure to compare the date listed in ADC with the date listed on the document to determine its relevance.
e. If the historical trend of the customer's purchases in the drug family shows consistent growth over last three (3) months.
f. Determine if the instance warrants the creation of a manual case for threshold adjustment to be made. If a manual case is required for this customer, do this within ADC by selecting Create Case to the right of the Early Dialogue Events screen. Follow the process for Objective and Subjective review.

c. Proactive Communication:
   a. Evaluate information provided by customer or sales and determine if additional details regarding the situation are needed. If so, reach back out through sales to collect this information. If customer or sales provides only an account number or store number, utilize the Store Lookup database, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, then opening the Store Lookup folder, and entering the appropriate information.
   b. Create a manual case within ADC if sufficient information provided by customer or sales by selecting Customer Search at the top of QRA Dashboard, typing in the customer's DEA #, displaying the customer record, selecting the Customer Cases tab of the Customer Details dashboard, and selecting Create Manual Case in the upper right corner. Follow the process for Objective and Subjective review. Instances where manual case creation is be necessary may include:
      i. The customer communicates that a pharmacy down the road is closing and it expects the need to increase its purchases by 15%. This 15% increase in purchases would cause threshold events, based on its current threshold for that drug family. The customer passes through objective criteria and subjective analysis.
      ii. The customer communicates that a recent theft has occurred and this has been confirmed through the documentation of a 106 – Theft Loss Report and a police report. Due to this confirmed theft, an increase for the month may be necessary.
      iii. The customer communicates that it will be or has started servicing new hospice facilities, requiring a pharmacist's review of available information.

Upon review the set of circumstances for each type of assessment, a decision should be made as to whether or not the scenario warrants an assessment. An assessment is required to increase a customer's threshold limit.

c. Assessment of the customer and its threshold is warranted in the following scenarios:
   i. The customer has not previously been assessed using the revised threshold limit methodology and policy. Customers who have previously been assessed will have documented comments from QRA personnel on the QRA Info tab of the Customer Details dashboard.

ii. Review of due diligence documents shows new information has been made available since the most previous review. New information could include a new site visit or change in business model as noted by the customer on a survey. Due diligence files will be listed in order from newest to oldest in the Customer-related Documents section on the Customer Profile tab of the Customer Details dashboard.

iii. A customer's orders significantly differ from previous orders (i.e. spike or increase in orders). Significant changes are defined when a Customer Zone has changed since previous assessment (if there has been one). Customer Zone will be documented during each review in the customer comments on the QRA Info tab of the Customer Details dashboard. Comparing the previously documented zone to the Customer Zone within the Tableau file will help determine if a change has occurred.

d. Assessment of the customer and its threshold is not warranted in the following scenarios[5]:

i. Review of due diligence documents indicates that no new information or due diligence has been made available since the most previous review. Due diligence files will be listed in order from newest to oldest in the Customer-related Documents section on the Customer Profile tab of the Customer Details dashboard.

ii. Notations have been made in the customer comments section to indicate that shipments above threshold limit are not to occur.

iii. The order is above threshold limit ending in pharmacist's designated static limit, ending in one or five (1 or 5). If review of due diligence documents show new information has been made available since the most previous review, an assessment would be warranted for this customer. Any proposed threshold limit for a customer who's current threshold ends in a 5 should be reviewed by the designated pharmacist, by assigning the case appropriately and including detailed comments.

iv. The customer has been terminated from purchasing controlled substance products from Cardinal Health. This will be noted within ADC and can be found by opening the customer case and reviewing the threshold listed on the Order Processing section of the screen. A customer who has been terminated from purchasing controlled substances products from Cardinal Health will have a threshold of one (1). This will also be noted within ADC as Current Status on the Customer Block/Reinstate tab of the Customer Details dashboard.

4. **Objective Assessment:** When it is determined that a customer and a threshold limit warrant additional assessment, the customer's objective criteria should be assessed. The objective criteria include a standardized set of metrics used to assess the customer's overall profile. The review of objective criteria generally includes the following steps:

a. Review customer specific Tableau file, specifically evaluating the following components:

[5] For held orders, this would result in the order being cut and reported as suspicious to the DEA.

a. Customer Zone of drug family or families triggering assessment.
b. Review trend of drug family or families triggering assessment, specifically evaluating spikes and underlying strengths.
c. Review objective criteria metrics, specifically evaluating the pass/fail score[6]. If a customer is part of the CIM and Profit Leader program, reference the score generated from that data to determine if the customer passes or fails. If the customer is not part of the CIM and Profit Leader program, reference the score generated from purchase data to determine if the customer passes or fails. The final score should be documented within ADC as a customer comment on the QRA Info tab of the Customer Details dashboard. Note: CVS, Kroger, and Walgreens are subject to a limited number of Objective Criteria (Oxy 15/30MG Gen, Hydro 10MG Gen, Alprazolam 2MG) due to their distribution position with Cardinal Health. For oxycodone and hydrocodone, if a change to the threshold sets it at 20,000 or higher, need to collect % Controlled information, which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the _____ folder, and choosing the appropriate information.
    i. When a customer fails the objective criteria:
        i. Within the Customer Comments section of ADC, document "Fail," reason(s) for failure, drug family and Customer Zone.
        ii. Within ADC, cut the order by selecting the Cut Order radio button found in the Order Processing section of the customer case screen.
        iii. Within ADC, report the order as suspicious by selecting the Report to DEA radio button found in the Order Processing section of the customer case screen.
        iv. Communicate the decision and the reasoning to the appropriate sales personnel. Email templates for communication can be which can be accessed on the I:drive by opening the Anti-Diversion Team Folder, opening the Customer Communication Templates folder, and choosing the appropriate communication.
            a. For Retail Independent customers, the communication should be sent to the PBC responsible for the customer. The sales rep can be identified within ADC on the Sales Rep tab of the Customer Details dashboard.
            b. For Retail Chain customers, the communication should be sent to the primary Cardinal Health sales contact responsible for the National Account. A complete list o contacts for each National Account can be identified found in Table 4: National Accounts Contact List.[8]
        v. Customers may receive a specified percentage of dosage units over their thresholds, once an accrual per drug family. The percentage allotted is dependent on the size of the customer and can be found in Table 5: Customer Release Percentage.[9] If this release percentage is utilized during an accrual period, it should

[6] See Appendix 3 for Objective Criteria and Score Model.
[8] See Appendix 4 for National Accounts Contact List.
[9] See Appendix 5 for Customer Release Percentage.

be noted, along with the drug family, within the Customer Comments section of ADC.

ii. When a customer passes the objective criteria:
  i. Within the Customer Comments section of ADC, document "Pass," reason(s) for failure, drug family and Customer Zone.
  ii. Proceed to the subjective review in Step 5.

5. **Subjective Assessment:** When it is determined that a customer passes the objective criteria, a subjective assessment of the customer and available information to assess the reasonableness of the information and underlying basis for the threshold limit increase. The review of subjective criteria generally includes the following steps:

a. Evaluate the order and historical order trend by reviewing customer's historical order pattern within the Tableau file to determine if the recent trend is reasonable and acceptable. Distribution and corresponding dosage unit quantity volume may be reasonable for the following reasons:
  I. Historical trend demonstrates consistent growth in the drug family over the last three (3) months.
  II. Historical trend demonstrates that the customer has not had any unjustified spikes in the purchase volume during the last six (6) months.
  III. The historical trend demonstrates that a shift in product purchasing/usage is evident. For example, a customer has begun purchasing less hydrocodone and has shifted these purchases to oxycodone.

b. Evaluate due diligence information by reviewing any information that has been made available within the last twelve (12) months. Review of any due diligence information outside of the twelve (12) month window is discretionary. As of right now, within ADC, the date associated with the document is the date on which it was loaded into Content Manager. Be sure to check the date the document was *created* in order to determine its relevance in the analysis process.
  a. If order pattern has significantly changed from historical order pattern and an unjustified spike is evident, communicate with sales team to collect necessary information to support the underlying change in ordering. Acceptable responses to support this type of change include:
    i. Business model changes, for example:
      i. A pharmacy down the street has closed and the customer will be picking up the demand.
        a. In instances where Sales proactively communicates this type of information, ask for information regarding the pharmacy's anticipated bump in purchases. If the customer responds with 10%, review historical purchases to determine whether the additional 10% in purchases will result in held orders. If so, and the customer has passed the objective criteria and subjective analysis, set or propose threshold based on Threshold Change Reference within Tableau. If the increase would cause the customer to change Customer Zone, assign the case to the designated pharmacist,

found in Table 7: Distribution Center Pharmacist Assignments.[11]

b. In instances where the customer does not proactively communicate this type of information and, as a result, is experiencing threshold events, review sales volume growth to help determine most appropriate threshold limit. If the customer has passed the objective criteria and subjective analysis, set or propose threshold based on Threshold Change Reference within Tableau. If the increase would cause the customer to change Customer Zone, assign the case to the designated pharmacist, found in Table 7: Distribution Center Pharmacist Assignments.[12]

ii. The customer will now be servicing new hospice, long-term care, pain management, or weight loss clinics. In these instances, assign the case to the designated pharmacist, found in Table 7: Distribution Center Pharmacist Assignments.[13] Share information pertinent to the customer, so that pharmacist can clinically review the held order.

b. Historical trend for the drug family, which can be found within the Tableau file on the Drug Family tab at the bottom of the screen. This may also be found within ADC by selecting the appropriate drug family listed next to Qty Shipped This Month (Dosage Units) found above the Order Processing section of the customer case screen. Situations where increased volume may be reasonable (non-exhaustive):

i. Trend shows consistent growth over the last three (3) months.

ii. Trend shows customer has not had unjustified spikes in purchase volume during the last six (6) months.

c. Distribution position, for CVS, Kroger, and Walgreens, which can be determined by reviewing Cardinal Health Distribution Position.[14]

d. Percentage of cash the customer accepts in regards to total prescriptions (controlled and non-controlled). If a customer reports that it accepts more than eleven percent (11%) cash for total prescriptions, communicate with sales team to understand this information at a more granular level. Ask the sales team to collect information regarding:

i. What percentage of controlled prescriptions are paid for in cash?

ii. What percentage of non-controlled prescriptions are paid for in cash?

e. On-site investigation reports

i. When available, on-site investigation reports should be referenced. The review of the report should determine if red-flags were identified during the visit. Within the Investigation Final Report, specifically pay close attention to:

a. those questions with Yes/No answers highlighted in red and the accompanying explanations;

---

[11] See Appendix 7 for Distribution Center Pharmacists Assignments.
[12] See Appendix 7 for Distribution Center Pharmacists Assignments.
[13] See Appendix 7 for Distribution Center Pharmacists Assignments.
[14] See Appendix 6 for Cardinal Health Distribution Position.

b. Section 2. Dispensing Information, specifically noting total prescription count and percentage of cash information,
c. Section 4. Know Your Customer, specifically noting the specialties serviced by the pharmacy and the percentage of total prescriptions for which these specialties account;
d. Section 5. Due Diligence, specifically noting the investigator's observations.

ii. Full-site visit reports, conducted by an investigator, can be found within ADC or Content Manager under the naming convention 110 – Investigation Final Report.
iii. Sales site visit reports, conducted by a PBC, can be found within ADC or Content Manager under the naming convention 102 – Sales Site Visit.

f. Affiliations (prescriber specialties)
   i. If available, this information will be noted in the customer's initial KYC or in new due diligence information collected since previous assessment. Within a 110 – Investigation Final Report, this information can be found in Section 4. Know Your Customer.
g. Upon receipt of information, if a pharmacist's opinion is needed, assign the case to the designated pharmacist, found in Table 7: Distribution Center Pharmacist Assignments.[15] To assign the case within ADC, select the "+" for the specific customer to drop down the specific case. Select Assign Case on far right and indicate the appropriate pharmacist whose review is requested. Pharmacist will then be responsible for reviewing the customer and proposing a threshold change, if warranted. A pharmacist's opinion may be needed because the customer has experienced a change in business model or sales has shared any other information indicating that a pharmacist's input would be beneficial in the decision making process.
h. If within three (3) days, no response has been received from the customer, the order is cut and reported to the DEA as suspicious. This can be accomplished within ADC for the specific Customer Case by selecting both the Cut and Report to DEA radio buttons, and then selecting Process, under the Order Processing portion of the screen.

6. **Eligibility for threshold limit increase:** If all objective and subjective criteria are satisfactory and a customer is eligible for threshold limit increase. The following steps should generally be completed to determine the appropriate limit to set the threshold limit.

a. Determine if a Sales Site Visit or QRA Site Visit it required by reviewing Table 2: Customer Segmentation and Review Responsibilities.[16] If a Sales Site Visit is required, it must have been completed within the last 90 days. If a QRA Site Visit is required, it must have been completed within the last 12 months.
   i. If a Sales Site Visit has not been completed within the specified period of time, request a site visit within ADC by opening the customer case, checking the Site Visit box at the bottom of the Order Processing screen,

[15] See Appendix 7 for Distribution Center Pharmacists Assignments.
[16] See Appendix 2 for Customer Segmentation and Review Policies.